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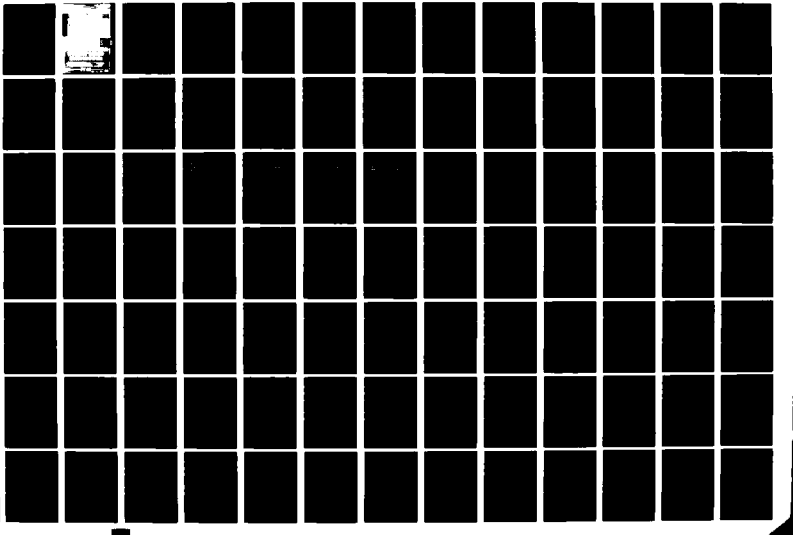

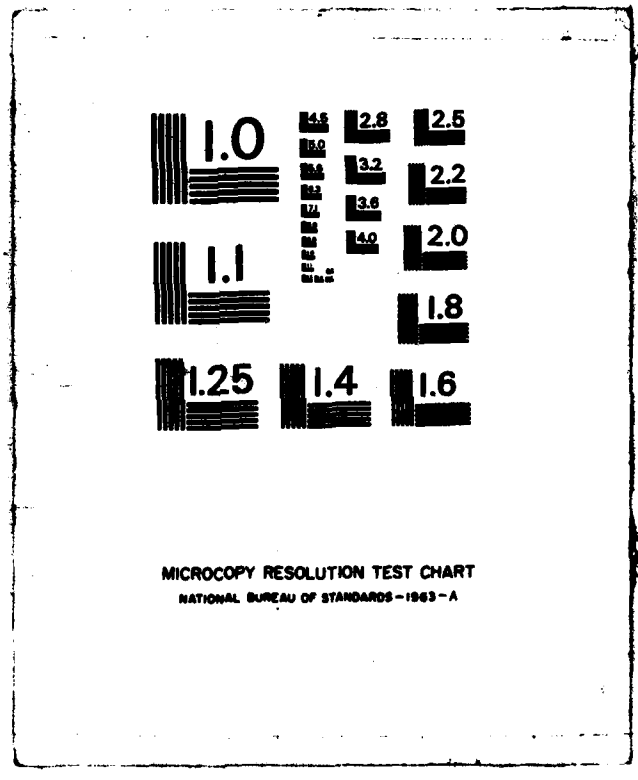
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CLINICAL INVESTIGATION PROGRAM REPORT

1 October 1982

CONTROL SYMBOL: MED-300

DEPARTMENT OF CLINICAL INVESTIGATION
DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER
FORT GORDON, GEORGIA 30905

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19. KEY WORDS (Continue on reverse side if necessary and identify by block number)
Unit Summary; Detail Sheet (Study Objective, Technical Approach, Progress, Status); Publications; Presentations.

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)
This subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1982, and other known publications and presentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented.

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FOREWORD

The history of medicine is marked by eras in which theory has stymied further experimentation. Medieval medical knowledge was dominated by the writings of the three giants pictured on the cover for this year. To know their texts was once the essence of being a physician. No questioning of their precepts was allowed.

The origin of classical medicine was quite practical. In the Iliad, Machaon and Podalirius were sons of Aesculapius who functioned as regimental surgeons and were quite human relative to their father. One of them as a surgeon was worth an army of men. The eventual successors of Aesculapius, however, became priests and preferred to rely on dreams and theory. This desire for physicians to assume a priestly role is illustrated in the gradual change in the insignia used. The original wand of Aesculapius has a single serpent and the inscription, "Life is short, art is long, experience is difficult." The dual serpent caduceus is instead the Herald's Wand of Hermes used to open doors between gods and men.

The three giants themselves each developed a unique blend of observation and principles. Hippocrates relied on both observation and wisdom and served as a counterbalance to the Pythagorean - Empedoclean theory of the four humors. Likewise Galen prepared himself well through training, wide experience, and experiments on animals. He once observed that "common sense" was a misnomer since it was far from common. Avicenna was honored for centuries for his ability to balance his philosphy with the wealth of experimental pharmacology accumulated by his predecessors including Rhazes. His great intellect served to codify existing knowledge with the tempering of a practical logician.

The error of medievalists lay not in falsely ascribing greatness to this triumvirate, but rather to missing the nature of their greatness. Each knew the importance of original observation as well as the value of systematicizing the knowledge. The prayer of Maimonides captures the essence of their greatness expressed as a humility and has been used for centuries as an ideal for physicians.

> "...Grant me strength, time and opportunity always to correct what I have acquired, always to extend its domain; for knowledge is immense and the spirit of man can extend infinitely to enrich itself daily with new requirements. Today he can discover his errors of yesterday and tomorrow he may obtain a new light on what he thinks himself sure of today...."

The opportunity for original investigation provides that tempering of theory through controlled observation. Throughout the centuries of medicine, military medicine has often provided the practical contributions that theoretical medicine has ignored.

Clinical Investigation at Dwight David Eisenhower Army Medical Center has enjoyed a growing role in forming our future and present physicians in this tradition. The burgeoning number of protocols contain many which represent the unique opportunities of military medicine near troop concentrations.

This effort has enjoyed the support and encouragement of two wise and compassionate physicians representing well this tradition in their respective roles, Brigadier General Frederick C. Biehusen, Commander and Colonel William L. Moore, Jr., Chief of Professional Services. The name of the latter can be noted as a principal investigator on several of the protocols contained herein.

The completion and occupation of newly remodeled space in the main hospital represents an important interim step toward a closer alliance of research and clinical practice at DDEAMC. The bulk of the Clinical Investigation's laboratory and animal space remains located in a remote and inadequate WW II frame structure. Despite the handicap of these substandard facilities, the staff of the department has remained, dedicated and productive, working to maintain the high standards of military medicine.

KENT M. PLOWMAN
MAJ(P), MC
Chief, Department of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1982

A. Objective.

The Department of Clinical Investigation is responsible to the Chief, Professional Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigations within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are connducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

Name	Rank	MOS	Title
Plowman, Kent, M.	MAJ	61F00	Chief
Arensman, John B.	MAJ	64A00	Veterinarian
Hannan, Charles J., Jr.	CPT	68Z00	Physiologist/Pharmacologist
Harris, Richard W.	CPT	68J00	Microbiologist
Sherman, Richard A.	CPT	68T9C	Psychobiologist
	E6	92B20	NCOIC
Jones, Frederick, Jr.	E6	91T20	Sen Animal Sp, Act'g NCOIC
Lohr, Edward M.	SP5	92D10	Chem Lab Sp
Blanco, Diana T.	SP5	01H20	Biological Science Asst
Jenkins, Nettie C.	SP5	74F20	Programmer/Analyst
Dinnigen, Diane	SP4	92B10	Med Lab Sp
Dunn, James C.L.*	SP4	91T10	Animal Sp
Parker, Laura	SP4	91T10	Animal Sp
Cook, Jeffery	PFC	91T10	Animal Sp
Horner, Jack A.	GM13	01320	Asst C, S. Res Histologist
McPherson, James C. III, PhD	GS11	01320	Biochemist
Patterson, Robert A.	GS9	00181	Psychology Technician
Prior, Robert	GS9	00644	Medical Technologist
Gladney, Diane	GS7	00404	Biological Lab Technician
Martinez, Rosina	GS6	01087	Editorial Assistant
Gladney, Jeanne M.**	GS4	00312	Clerk Steno
Bryant, Cheryll	GS4	00312	Clerk Steno
Holmes, Essie M.	GS5	00404	Biological Lab Tech (Temp)
Silas, Bill E.	WG5	07706	Animal Caretaker

*PCS June 1982
**Transferred March 1982

D. Funding.

Type	Fiscal Year 81	Fiscal Year 82
Civilian personnel to include benefits	147,738.00	195,713.00
Consumable supplies	76,614.00	102,881.00*
Civilian contracts to include consultants	200.00	1,500.00
TDY	7,793.00	10,989.00
Publications	1,055.00	1,934.00
Noninvestment equipment (Minor MEDCASE)	2,902.00	3,144.00
Other OMA	20,638.00	36,763.00
OMA Total	23,539.00	49,907.00
MEDCASE	132,403.00	179,463.00
Other	57.00	3,176.00
Military	225,762.00	279,884.00
Total	638,751.00	815,447.00

*Includes $13,000 for furniture for two new laboratories.

E. Progress.

Protocol Disposition FY 82

	Completed	Terminated	Ongoing to FY 83
FY 78	-	2	3
FY 79	1	2	6
FY 80	1	6	6
FY 81	4	7	20
FY 82	16	1	35
	22	18	70

In addition to the above FY 82 total, two protocols are still going through TSGO review; two are pending approval from HSC; and one in "hold" status awaiting new PI.

F. Problems.

The fundamental problems remaining for clinical investigation are the same ones previously identified: 1) a dilapidated, hazardous laboratory located one kilometer from the main hospital; 2) a shortage of adequate animal facilities; 3) obsolescent equipment; and 4) delays in filling critical personnel positions. Significant progress continues to be made despite periodic setbacks.

TABLE OF CONTENTS

***

Code:

O - Ongoing
C - Completed
T - Terminated

P - Published
PR - Presented

PUBLICATIONS FY 82

DEPARTMENT OF CLINICAL INVESTIGATION

McPherson JC Jr, McPherson JC III. The effect of intravenous pluronic polyols F-38, F-68, F-77, and F-127 on voluntary food consumption in the rat (Abstract #42). Soc Exper Biol Med 1981; 6:13. (C)

McPherson JC III. Pluronic polyols as new experimental hyperlipemic agents in the rat (Abstract #8603). Fed Proc 1982; 41:1741. (C)

Horner JA, McPherson JC III, McPherson JC Jr. Food intake an intravenous pluronic polyols in the rat (Abstract #4290). Fed Proc 1982; 41:1003. (C)

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Horner JA, McPherson JC III, McPherson JC Jr. The correlation of the pathohistological effects and physiologic effects of pluronic P-105 in rats (Abstract). Ga J Sci 1982; 40:33. (C)

Prior RW, McPherson JC III, McPherson JC Jr. Pluronic F-88 as a therapeutic agent in fat embolism (Abstract). Ga J Sci 1982; 40:33-34. (C)

Jones F Jr, Arensman JB, McPherson JC III, McPherson JC Jr. Hemolytic activity of some non-ionic surface active agents (NISAA) (Abstract). Ga J Sci 1982; 40:32. (C)

McPherson JC Jr., McPherson JC III. Evaluation of pluronic F-68 as a potential prophylaxic agent for treating fat embolism syndrome (Abstract #5000). Fed Proc 1982; 41:1128. (C)

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McPherson JC Jr., McPherson JC III. Studies on the mechanism of the delayed gastric emptying following intravenous Triton W-1339 (Abstract). Res Sec 1982; 6:12-13. (C)

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ACCEPTED

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Sherman RA, Tippens JK. Suggested guidelines for treatment of phantom limb pain. Clin Orthopedics and Related Research. (C)

Sherman, RA, Sherman CJ. Prevalence and characteristics of chronic phantom limb pain among American veterans: Results of a trial survey. Am J Phy Med. (C)

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Kulangara RJ, Boineau JP, Moore HV. Electrovectorcardiographic features of tricuspid atresia. In: Rao PS, ed. Tricuspid atresia. New York: Futura, 1982; 113-126.

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PUBLICATIONS

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

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Giordano FL. Dealing with the difficult patients. Accepted by Charles C. Thomas Co. 1982.

Walters GD. Schizophrenia and the MMPI: A review. Accepted by Schizophrenia Bulletin. (C)

Shivers WF. A command consultation model for community mental health activities. Accepted by Mil Med.

DEPARTMENT OF SURGERY

Edwards FH, Davies RS. Late post-traumatic obstructive jaundice secondary to a biliary tract foreign body. J Trauma 1982; 22(4):336-338.

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Dales RL, Garcia JC, Davies RS. Papillary-cystic carcinoma of the pancreas. Accepted by J Surg Oncol.

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Harris RW, Arensman JC, Moore WL. Penetration and efficacy of maxalactam in a rabbit whiffle-ball abscess model. Interscience Conf Antimicrobial Agents and Chemotherapy, Chicago, IL, November 1981. (C)

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Prior RW, McPherson JC III, McPherson JC Jr. Pluronic F-88 as a therapeutic agent in fat embolism. Georgia Academy of Science, Columbus, GA, April 1982. (C)

Jones F Jr., Arensman JB, McPherson JC III, McPherson JC Jr. Hemolytic activity of some non-ionic surface active agents (NISAA). Georgia Academy of Science, Columbus, GA, April 1982. (C)

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Sherman RA. Phantom Limb Pain. Georgia Psychological Assn, Augusta, GA May 1982. (C)

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Armitage DT. Legal aspects of the impaired physician. Tripler Army Medical Center, Honolulu, HI, April 1982.

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Armitage DT. Current trends in psychiatric education. Georgia Psychiatric Assn, Atlanta, GA, February 1982.

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Hagen DM. Quality assurance in social work. Army Social Work Conference, San Antonio, TX, February 1982.

Hatcher RW. Family as the unit of health care. Georgia-wide Tell-net communication to medical treatment facilities. Five presentations in the Spring 1982 broadcast from the University Hospital, Augusta, GA.

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Dales RL, Davies RS. Neurofibromatosis and neurofibrosarcoma: Update on biological behavior and surgical implications. Gary Wratton Surgical Symposium, WRAMC, Washington, DC, April 1982.

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PRESENTATIONS

Ingeman PL. Cellular team concept for utilization of occupational therapy personnel in the theater of operations. Occupational Therapy Educational Supervisors Conference FAMC, March 1982.

Riffle JE. Scleral buckling for longstanding retinal detachments. Washington Hospital Center Retinal Symposium, Washington, DC, April 1982.

Bender DR. Review of CHAMPUS hearing handicap criteria. Military Audiology Seminar, Los Angeles, CA, November 1981.

Wikert GA. Evaluation of the coagulation and fibrinolytic systems in patient undergoing TRUP. Society of Government Services Urologists, 29th ann Kimbrough Urological Seminar, Denver, CO, November 1981. Awarded second prize in resident paper competition.

DEPARTMENT OF NURSING

Newton T. Report of research on heparin locks. Phyllis Verhonick Research Symposium. AHS, Ft Sam Houston, TX, June 1982.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 78-5	Status: Ongoing

Title: A Vascular Occlusion Stroke Model: I. A Technique for Evaluating Therapeutic Approach and Predisposing Factors.

Start Date: Feb 78		Est Comp Date:
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate predisposing factors and experimental therapies in the gerbil model of cerebral ischemic stroke.

Technical Approach: Surgical occlusion of the left common carotid and restriction of flow in the left was employed to produce an experimental model of stroke. More details may be found in Protocol 82-34.

Progress: A number of neuropharmacological approaches were attempted in order to determine if the devastating effect of thyrotropin releasing hormone (TRH) (see Protocol 82-34) was related to any neurotransmitter systems. Manipulation of the brain levels of acetylcholine, norepinephrine, serotonin, dopamine and some combinations of these were without effect on the morbidity and mortality of stroked gerbils administered TRH. Further work is planned to evaluate the role of the known TRH effect on serum glucose in the stroke model.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 78-12	Status: Terminated

Title: Stroke Model: III. The Effect of Dexamethasone Therapy.

Start Date:		Est Comp Date:
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate dexamethasone with DMSO vehicle as an experimental therapy in the gerbil stroke model.

Technical Approach:

Progress: Although this study still has scientific merit, the available resources of time and personnel demand priority be given to other related projects (see Protocol 78-5) at the present and in the coming year. Study is terminated.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 78-36	Status: Terminated

Title: Stroke Model: IV. The Response of Brain Superoxide Dismutase to Ischemia.

Start Date:		Est Comp Date:
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC		**Facility:** DDEAMC
Dept/Svc: Clinical Investigation		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To measure activity of brain superoxide dismutase in gerbil brain made ischemic for various periods of time.

Technical Approach:

Progress: Although this study still has scientific merit, the available resources of time and personnel demand priority be given to other related projects (see Protocol 78-5) at the present and in the coming year. Study is terminated.

Detail Summary Sheet

Date 20 Oct 82	Prot No.: 79-7	Status: Ongoing

Title: Control of Gonadotropin Secretion in the Male Rat.

Start Date: May 79		Est Comp Date:
Principal Investigator: James C. McPherson III, PhD, DAC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words: Gonadotropins Steroids		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the role of estrogens, progesting and androgens either alone or in combination in the regulation of gonadotropin secretion.

Technical Approach: Immature male rats are castrated and given replacement steroid therapy beginning immediately and continuing for five days. Neonatally androgenized female rats are castrated and given replacement steroid therapy beginning immediately and continuing for five days, assessed for pituitary sensitivity to LHRH, or ovarian hypertrophy. At the end of the treatment period, the animals are sacrificed, blood drawn and secondary sex organs removed and weighed as a measure of biological activity of the steroids. Blood and/or tissue samples are analyzed for serum gonadotropins and/or steroids by radioimmunoassay.

Progress: The dose related effect of a single injection of progesterone on pituitary sensitivity to LHRH in estrogen-primed castrate male rats was examined. Dose dependent stimulatory and inhibitory doses of progesterone were identified for both FSH and LH. Changes in pituitary content of FSH and LH were observed. Although hypothalamic influences of such treatments cannot be ruled out, the evidence indicates that significant modulation of gonadotropin synthesis and release by progesterone occurs at the level of the pituitary. Progesterone may modulate gonadotropin secretion in estrogen-primed rats by altering the pituitary sensitivity to LHRH along with possible hypothalamic effects.

Neonatally androgenized female rats which were castrated and administered various doses of estradiol were assessed for pituitary sensitivity to estrogen as reflected by suppression of gonadotropin levels and for biological activity of the estradiol by uterine weight gain. These results are under evaluation at this time.

Detail Summary Sheet

Date 20 Oct 82	Prot No.: 79-19	Status: Ongoing

Title: Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying.

Start Date: Jan 80		**Est Comp Date:**
Principal Investigator: James C. McPherson III, PhD, DAC		**Facility:** DDEAMC
Dept/Svc: Clinical Investigation		**Associate Investigators:** James C. McPherson, Jr., M.D., Med College of Georgia
Key Words: Gastric emptying; Surfactants; Gastric secretion		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To determine the effect of non-ionic surface active agents on gastric emptying, voluntary food consumption, body weight and blood chemistries.

Technical Approach: Groups of fasted rats were given non-ionic surface active agents followed 30 minutes later by a commercial rat tube feeding diet. Animals were sacrificed at various times after feeding and gastric emptying compared to control groups. In another series of experiments, rats were injected daily for four days with non-ionic surface active agents. Voluntary food consumption before and during treatment was measured. Twenty-four hours following the last injection, the animals were sacrificed and blood drawn for blood chemistries. In an additional series of experiments the effect of non-ionic surface active agents on gastric secretion is being assessed.

Progress: The effect of pluronic polyols on voluntary food intake was studied. Blood was analyzed for cholesterol, triglycoride and glucose levels. Voluntary food consumption was decreased by pluronic polyols P-105 and F-127. Only these polyols had elevated blood lipid levels. Pluronic polyols F-77 and F-88 had moderately elevated blood lipid levels. The mechanism of food intake control can most likely be explained on the basis of the lipolystatic theory of appetite. The observed decreased voluntary food intake lead to further studies which show a delayed gastric emptying time in these animals and also an apparent increase in gastric secretion. These findings are being further investigated.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 79-21	Status: Ongoing

Title: The Experimental Fat Embolism Syndrome: An Electron Microscopic Study of Lung in Three Models.

Start Date: Jun 80		Est Comp Date:
Principal Investigator: Jack A. Horner, B.S., DAC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson III, PhD, DAC James C. McPherson, Jr., M.D., Medical College of Georgia
Key Words: Fat Embolism Electron Microscopy		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $1200.00	Periodic Review Results

Study Objective: Experimental fat embolism syndrome is usually induced by one of five techniques: 1) fracture of the femur of an animal, 2) injection of extracted or homogenized adipose tissue from a same species donor, 3) injections of olive oil or purified triolein, 4) injection of oleic acid, or 5) injection of mineral oil (all injections given intravenously). In this study the similarity and differences, if any, in these last three techniques (olive oil, oleic acid, and mineral oil) will be investigated.

Technical Approach: Fat embolism is a major (although frequently undiagnosed unless severe) complication in patients with fractures of the long bones and/or severe trauma. The etiological mechanism of this syndrome is still unsettled. The two mechanisms most widely accepted are: 1) fat from the bone marrow of fractured bones or traumatized adipose tissue enter into small broken veins and travel to the lung where blockage of the capillaries and arterioles occur, and 2) after trauma, the circulating lipoproteins in blood coalesce to form globules of fat large enough to block the capillaries of the lung. In addition, once the fat has blocked a capillary or arteriole, the pathogenic events which follow are unclear. The major effect may be a simple blockage, but some investigators believe the most harmful effects result from the release of free fatty acids from the "trapped" fat globules in the lung. This study will attempt to establish the differences which could be important in the clinical syndrome by examining a mineral oil model (pure blockage with no possible release of free fatty acid from the globules), oleic acid (effect of free fatty acid only), and olive oil (fat capable of hydrolysis to yield free fatty acids). This study may add to our basic understanding of the events in the pathogenesis of the clinical fat embolism syndrome and suggest the basis of new methods of treatment.

Progress: With the move of the Electron Microscopy Section to new facilities and the subsequent improvement in instrument performance, superior micrographs are being produced of pulmonary tissue. This has permitted a full resumption of this study. Hexadecene -1 has been substituted for mineral oil and has resulted in an osmophilic blocking agent which we are able to visualize in the EM. The recently installed new scanning electron microscope is permitting excellent visualization of the emboli as revealed by the Humphrey/Spurlock ethanol cryofracture method.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 79-23	Status: Ongoing

Title: Examination of Multi-Microbial Abscesses in Animal Models: II. Morphological and Bacteriological Comparison.

Start Date: Oct 82		Est Comp Date:
Principal Investigator: Richard W. Harris, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators: Jack Horner, B.S., DAC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine bacteriological and physiological parameters of an animal abscess model involving continuous sampling.

Technical Approach: To examine the morphological definition of abscesses by scanning electron microscopy during the development of the abscess.

Progress: With the delivery of a new scanning electron microscope, improved resolution and the elimination of building vibration, this study can now be initiated.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 79-35	Status: Ongoing

Title: Rapid Diagnosis of Viral Respiratory Infection.

Start Date: Feb 80	Est Comp Date:
Principal Investigator: David R. Haburchak, M.D., LTC, MC	Facility: DDEAMC
Dept/Svc: Medicine Clinical Investigation	Associate Investigators: Richard W. Harris, CPT, MSC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results Mar 82 Continue

Study Objective: To determine feasibility of rapid viral diagnosis in patients with ARD by methods of direct electron microscopy and enzyme-linked immunoabsorbant assay.

Technical Approach: Throat swabs from patients with ARD are inoculated into holding medium, split, cultured, processed for EM and ELISA.

Progress: Samples are presently being stored frozen that were obtained for routine viral isolation. Materials for immunoassay are being ordered.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 79-36	Status: Terminated

Title: Chronic Medications and HDL-Cholesterol Screen.

Start Date: Aug 80		Est Comp Date:
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation, Family Practice, Medicine		Associate Investigators: J. Paul Martin, M.D., MAJ, MC William L. Moore, Jr., M.D., COL, MC Edward Mendoza, M.D., LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Jul 82 Terminate

Study Objective: To monitor the effect of chronic medications on plasma high density lipoprotein cholesterol (HDL-Chol).

Technical Approach: Plasma level of HDL-Chol is determined in volunteers before beginning a chronic (greater than 3 week) program of a drug followed by a post drug HDL-Chol level.

Progress: No patients have been entered into this protocol during the current fiscal year, while three have been entered over the entire course of the study. Few patients meet the entry requirements and the necessary followup further reduced the availability of useful data.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 80-13	Status: Terminated

Title: Natural Occurring Immunoglobulins in Human Serum to Bacteroides fragilis.

Start Date: Mar 80	**Est Comp Date:** Sep 82
Principal Investigator: Richard W. Harris, CPT, MSC	**Facility:** DDEAMC and VA Medical Center
Dept/Svc: Clinical Investigation	**Associate Investigators:** T.B. Buxton, ASCP, VAMC J.P. Rissing, M.D., VAMC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the IgM and IgG serum levels in a population of normal healthy human subjects using enzyme linked immunosorbent assay.

Technical Approach: Serum from 200 blood donors will be collected and double antibody sandwich immunoassay technique using lipopolysacchride of Bacteroides fragilis as the solid phase will be performed using antisera to human IgG and IgM.

Progress: This study was not initiated because of technical difficulties in obtaining a sensitive conjugate for IgM and should be terminated.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 80-18	Status: Ongoing

Title: Conduit From Thoracic Duct to Esophagus: Application of New Surgical Procedure.

Start Date: Mar 80	**Est Comp Date:**
Principal Investigator: J. Bruce Arensman, DVM, MAJ, VC	**Facility:** DDEAMC
Dept/Svc: Clinical Investigation	**Associate Investigators:** A.L. Humphries, M.D., Medical College of Georgia
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative CMA Cost:**	**Periodic Review Results**

Study Objective: To prove the efficacy of the proposed surgical procedure and to make a practical application of it. The flow of lymph into the gastrointestinal tract will result in destruction of lymphocytes and reduction of serum IgG and IgA levels to create a form of immunosuppression.

Technical Approach: Using the left jugular vein and right carotid artery, an A-V fistula is formed with the carotid artery routed through the esophageal musculature in proximity to the submucosa. In a second operation, two weeks later, the carotid and brachiocephalic vein are ligated and the lumen of the carotid opened into the esophageal lumen. Lymph can then flow from the thoracic duct through the jugular, through the transplanted carotid, into the esophagus.

Progress: No significant work has been conducted on this project during this FY because of lack of available time on the part of Dr. Humphries.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 80-29	Status: Ongoing

Title: Differentiation of Bacteria *in vivo* by Gas Liquid Chromatography.

Start Date: Nov 81	**Est Comp Date:**
Principal Investigator: Richard W. Harris, CPT, MSC	**Facility:** DDEAMC
Dept/Svc: Clinical Investigation	**Associate Investigators:** J. Bruce Arensman, DVM, MAJ, VC William L. Moore, Jr., M.D., COL, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine patterns of metabolite production by electron capture gas chromatography in an abscess animal model.

Technical Approach: Exudate from the rabbit model will be used to compare monomicrobial abscesses. Organisms will be implanted with soft agar and exudate will be examined upon abscess formation. Serum will be drawn for determination of metabolites.

Progress: This study will be initiated as soon as two columns for the chromatograph arrive. They are presently on order.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 80-30	Status: Completed

Title: Detection of B. fragilis Antigen in vivo.

Start Date: Oct 80	Est Comp Date: Mar 82
Principal Investigator: Richard W. Harris, CPT, MSC	Facility: DDEAMC and VA Medical Center
Dept/Svc: Clinical Investigation	Associate Investigators: William L. Moore, Jr., M.D., COL, MC J. Bruce Arensman, DVM, MAJ, MC J. Peter Rissing, M.D., VAMC Thomas B. Buxton, M.S. (ASCP), VAMC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To use the enzyme linked immunoassay (ELISA) to detect B. fragilis in serum in an animal model.

Technical Approach: Two separate determinations will be made: a) detection of antigen in a rat bacteremia model; and b) detection of antigen in a rabbit abscess model.

Progress: The results of this study for detection of B. fragilis antigen in serum in a rat abscess model have been completed and were published in the Nov 81 issue of Clinical and Laboratory Medicine. The results for detection of antigen in the same model in urine have been completed. Antigen was found to be detected in rats infected with both laboratory and clinical strains of B. fragilis. Control rats and rats infected with various enterobacteraceae species were not detected. Detection was limited to 24-60 hours after initial infection. This study is now being continued in humans as protocol #82-47. Results of the detection of antigen in urine will be presented at the Oct 82 meeting of the Interscience Conference for Antimicrobial Agents and Chemotherapeutics, and submitted to Infection and Immunity for publication.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 81-16	Status: Ongoing

Title: Correlations Between Amount of Information Feedback and Success of Biofeedback Treatments.

Start Date: Feb 81	**Est Comp Date:** FY 83
Principal Investigator: Richard A. Sherman, PhD, CPT, MSC	**Facility:** DDEAMC
Dept/Svc: Clinical Investigation, Psychology Service	**Associate Investigators:** Ralph Bruno, PhD, CPT, MSC
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results** Mar 82 Continue

Study Objective: To determine whether increasing the amount of information about muscle tension given to patients with muscular control problems will shorten treatment times and increase the overall effectiveness of the treatment.

Technical Approach: For patients with Bruxism, half receive muscle tension feedback from the masseter muscle, weekly in the laboratory, and wear a masseter tension monitor nightly at home. The other half does the same with the addition of receiving feedback from the night monitor when they begin tensing their jaws. For patients with subluxation of the patella, muscle tension in the vastus medialis and lateralis will be recorded. Half will receive a combined feedback proportional to their relative tension and half will receive two independent signals juxtaposed in various ways indicating both relative and absolute muscle tension.

Progress: Eight subjects enrolled in FY 82; 24 subjects enrolled to date. All equipment for the subluxation portion of the study is now here and functioning. The counters for the ambulatory EMGs required for evaluation of nocturnal bruxism still have not been completed. Patients are using the units by counting feedback signals manually.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 81-17	Status: Ongoing

Title: Intrasession Psychophysiologic Arousal Correlates of Psychotherapy and Behavior Treatment.

Start Date: Feb 81	**Est Comp Date:**
Principal Investigator: Richard A. Sherman, PhD, CPT, MSC	**Facility:** DDEAMC
Dept/Svc: Clinical Investigation, Psychiatry & Neurology	**Associate Investigators:** John McCormack, PhD, LTC, MSC William G. Bissell, M.D., LTC, MC Ralph Bruno, PhD, CPT, MSC
Key Words: Arousal Psychotherapy	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Mar 82 Continue

Study Objective: To monitor patterns of arousal among patients undergoing group psychotherapy, individual psychotherapy, or individual behavior therapy to detect correlations between therapeutic work/intervention and arousal (as reflected by psychophysiologic parameters) during a session.

Technical Approach: Patients in the above settings will be instrumented appropriately so that various psychophysiologic parameters indicative of arousal (heart rate, respiration rate, number of GSR's, muscle tension, peripheral vasoconstriction, etc.) can be continuously monitored throughout a session. All verbal interactions will be recorded on a second by second basis on the physiologic data tape to permit correlation between arousal and therapy.

Progress: On hold waiting for a technician to be assigned capable of carrying out the technical portion of the study.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 81-18	Status: Ongoing

Title: Environmental Stress and Electromyographic Correlates of Chronic Posterior Trunk Muscle Pain.

Start Date: Feb 81		**Est Comp Date:**
Principal Investigator: Richard A. Sherman, PhD, CPT, MSC		**Facility:** DDEAMC
Dept/Svc: Clinical Investigation, Psychology, Orthopedics		**Associate Investigators:** John McCormack, PhD, LTC, MSC Jack K. Tippens, M.D., COL, MC
Key Words: Low back pain Upper back pain Muscle tension		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results** Mar 82 Continue

Study Objective: To record those muscles in the posterior trunk of patients with lower and upper back, shoulder, or neck pain related to abnormal muscle tension in order to ascertain relationships between stress, pain, and tension as well as evaluate the effectiveness of muscular relaxation training as a treatment for these problems. The relative effectiveness of these treatments for pain in the above areas with and without underlying muscle tension problems will be evaluated.

Technical Approach: Recordings of muscle tension; objective psychosomatic measures of stress, anxiety, functional locus and other factors; discomfort logs; and other measures will be made before, during and after muscle relaxation treatments of individuals with the problems described above. These progressive measures will be compared with identical measures made of individuals with: 1) musculoskeletal related pain in other areas; 2) high anxiety but no musculoskeletal pain; and 3) posterior trunk pain but no muscle tension problem. A second phase of the study will consist of continuous muscle tension recordings made throughout the day using wearable EMG recorders. These measures will be related to a continuously tape recorded log of environmental loci and stresses.

Progress: A total of 33 subjects have participated in the program, 7 in FY 82, but the cases have been so complex that hospital staff will be used to provide normal and abnormal baseline data.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 81-19	Status: Ongoing

Title: Investigations of Chronic Phantom Pain.

Start Date: Feb 81	**Est Comp Date:** Jan 85
Principal Investigator: Richard A. Sherman, PhD, CPT, MSC	**Facility:** DDEAMC
Dept/Svc: Clinical Investigation	**Associate Investigators:** Norman Gall, M.D., AMVAH San Antonio Andree J. Lloyd, PhD, VAMC, Augusta Jack K. Tippens, M.D., COL, MC, DDEAMC
Key Words: Phantom pain	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results** Mar 82 Continue

Study Objective: To 1) develop an understanding of the underlying causes of phantom pain; 3) determine the extent of phantom pain among the amputee population; 3) develop comparative differential profiles of amputees with and without phantom pain; and 4) evaluate new treatments of phantom pain.

Technical Approach: All service connected amputees who can be located receive a mail survey requesting information about their amputation, stump pain, phantom pain, etc. All service connected veterans living near DDEAMC and all amputees treated at DDEAMC or VAMC Augusta are asked to participate in a psychometric and psychophysiologic profile. All phantom pain patients seen at any participating center receive the same profile as part of the pretreatment workup.

Progress: Eleven patients have been seen this year, but we cannot conduct most evaluations because the thermography equipment required to carry out the profiles is not available yet. This portion of the project will remain at a low rate until the above apparatus is available. A survey of 6,300 amputee veterans has been completed. A civilian survey is now in progress.

Sherman R and Sherman C. Prevalence and characteristics of chronic phantom limb pain among American veterans: Results of a trial survey. Accepted by the Am J Physical Medicine.

Sherman R and Tippen JK. Suggested guidelines for treatment of phantom limb pain. Accepted by Clinical Ortthopedics & Related Research.

Review Article Based on Sherman RA Research:
Holly, M. Only the limb is phantom; the pain is real. Aches and Pains, 3(6): 20-25, 1982.

Detail Summary Sheet

Date 20 Oct 82	Prot No.: 81-42	Status: Ongoing

Title: Experimental Fat Embolism Syndrome: Basic Studies and Evaluation of Currently Available Therapies and New Agents.

Start Date: Oct 81		Est Comp Date:
Principal Investigator: James C. McPherson III, PhD, DAC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators: Jack A. Horner, DAC J. Bruce Arensman, DVM, MAJ, VC Robert Prior, DAC
Key Words: Fat embolism Surfactants		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Evaluation of current therapies and new therapies for treatment of fat embolism syndrome in an experimental animal model.

Technical Approach: Groups of male rats are pre-treated with IV injections of various non-ionic surface active agents using an initial dose level of 800 mg/kg B.W. 30 min later various doses of olive oil will be injected IV. An LD_{50} will be determined to assess the effect of the surfactants. Toxicological, pathological and metabolic studies will be conducted for each non-ionic surface active agent found to be effective in the treatment of experimental fat embolism

Progress: Pluronic polyol F-68 has been identified as effective in the treatment of experimental fat embolism. Additional pluronic polyols have been identified as non-hyperlipemic, hyperlipemic of short duration (return to normal after 24 hrs) or hyperlipemic of long duration. These agents may be useful in screening hypolipemic drugs. Several pluronic polyols were assessed for effects on blood constituents. Hemolytic activity of some of the surfactants has been assessed. Pathohistological effects of these agents are being conducting by looking at light and electron microscopic samples of lung, liver, kidney, spleen and heart (control) tissues.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 82-20	Status: Ongoing

Title: Correlations Between Extent of Patient Involvement and Effectiveness of Published Behavioral Treatments of Hypertension.

Start Date: Nov 81		Est Comp Date: Nov 83
Principal Investigator: Richard A. Sherman, PhD, CPT, MSC		Facility: DDEAMC
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words: Patient involvement Hypertension Behavioral treatment		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether the extent of patient in behavioral treatment of hypertension affects treatment success.

Technical Approach: The methods and results sections of all published articles on behavioral treatment of hypertension containing sufficient detail to permit analysis are sorted into "blind" booklets for rating. Physician and PhD groups are asked to "blind" rate each method and result section without knowing which are related to each other.

Progress: Packets for reviews are being prepared.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 82-43	Status: Ongoing

Title: Development of an Animal Model of Phantom Pain.

Start Date: Jul 82		**Est Comp Date:** Jul 83
Principal Investigator: Richard A. Sherman, PhD, CPT, MSC		**Facility:** DDEAMC
Dept/Svc: Clinical Investigation		**Associate Investigators:** Jack K. Tippens, M.D., COL, MC J. Bruce Arensman, D.V.M., MAJ, VC Charles J. Hannan, Jr, PhD, CPT, MSC Mrs. Crystal Sherman, M.S.
Key Words: Phantom pain Animal model Rat		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To develop an animal model of phantom pain.

Technical Approach: Rats are trained to respond to gentle, harmless, shocks by pressing different levers depending on where along the foreleg the shock is given in order to receive a milk reward. After training is successful, the foreleg is amputated by a combined veterinary-orthopedic surgery team while the animal is under anesthesia. Following recover, the shocks are presented to the remaining portion of the foreleg. The number of responses to stimulation of areas no longer present are compared with the previous number of incorrect responses.

Progress: None, waiting for equipment.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 82-44	Status: Ongoing

Title: Biochemistry of Acute Psychosis.

Start Date: Jun 82	**Est Comp Date:**
Principal Investigator: Charles J. Hannan, Jr., PhD, CPT, MSC	**Facility:** DDEAMC
Dept/Svc: Clinical Investigation, Psychiatry	**Associate Investigators:** William F. Shivers,Jr, M.D., LTC,MC G. Fraklin Carl, PhD, VAMC Alan Boulton, DSc, Univ Hospital, Saskatoon, Canada
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: Through a multicenter cooperative effort, biochemical measurements will be made on blood fractions obtained from DDEAMC psychiatric patients, and these results will be correlated with symptomatology.

Technical Approach: Study design will be composed of four parts: a) psychiatric diagnostic criteria and coordination of referral sources for inclusion of subjects and controls; b) collection, fractionation and distribution of blood products to investigators; c) biochemical determination on blood fractions by investigators; d) collection and analysis of data considering diagnostic information and two month follow up of subjects.

Progress: No patients have yet been entered in this study. Our planned beginning date for patient entry is Nov 82. Coordination of sources of patients with the investigators, logistics of getting biological samples to appropriate co-investigators and establishing the assay validity have occupied the efforts of the study investigators up to this time.

Detail Summary Sheet

Date 18 Oct 82	**Prot No.:** 82-47	**Status:** Ongoing

Title: Detection of Bacteroides fragilis Antigen in Human Serum and Urine by Immunoassay.

Start Date: Oct 82	**Est Comp Date:**
Principal Investigator: Richard W. Harris, CPT, MSC	**Facility:** DDEAMC
Dept/Svc: Clinical Investigation	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To determine if Bacteroides fragilis antigen(s) can be detected by immunoassay in patients with documented B. fragilis infections. Urine and serum will be sampled for antigen.

Technical Approach: Patients that are culture positive for B. fragilis will be asked to participate in the study. One serum and three urines will be obtained over a one-week period. 24-hour urines will be obtained. Urine will be dialyzed and analyzed by an indirect immunosorbent assay specific for B. fragilis outer membranes.

Progress: No appropriate patients have been selected at this point in the study.

Detail Summary Sheet

Date 20 Oct 82	Prot No.: 80-3	Status: Terminated

Title: Penetration of Topically Applied Carbon 14 Tagged 2% Lidocaine on Dog Oral Mucosa.

Start Date: Feb 80	**Est Comp Date:** Sep 82
Principal Investigator: Andrew D. Chandler, DDS, CPT, DC	**Facility:** DDEAMC
Dept/Svc: Dental Activity, Clinical Investigation	**Associate Investigators:** Charles J. Hannan, Jr., PhD, CPT,MSC James C. McPherson III, PhD, DAC
Key Words: Lidocaine Adsorption	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To establish an experimental animal model to assess the rate of uptake of topically applied anesthetics.

Technical Approach: A jelly containing C^{14} labelled lidocaine-Hcl was placed in a defined area of the mandibular vestibular attached gingiva of a dog. At appropriate time intervals the jelly was removed and two 3mm biopsies taken from each area. Tissue samples were digested and counted for carbon-14

Progress: Four dogs were utilized to assess uptake of C^{14} labelled lidocaine Hcl as a function of time. Technical difficulties had to be overcome which resulted in delays and developing new procedures for measuring related parameters which affect anesthetic uptake.

Detail Summary Sheet

Date 23 Sep 82	Prot No.: 82-25	Status: Completed

Title: Sensory Input Towards Anxiety in the Dental Clinic.

Start Date: Feb 82	**Est Comp Date:** Jun 82
Principal Investigator: David B. Gibson,, CPT, DC	**Facility:** DDEAMC
Dept/Svc: Dentistry/Tingay Dental Clinic	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To determine which of the five major senses, when stimulated, most leads to anxiety in the dental clinic.

Technical Approach: All clinical data will be gathered at Tingay Dental Clinic. One hundred patients will participate in the study. By use of an anonymous questionnaire, information will be gathered to rank sensory stimuli and then allow the patients to indicate a specific incident under each major sense that bothers them. Patients will be studied in the reception area of the clinic prior to any treatment. The questionnaires will then be taken up by a neutral assistant. The data will be transferred to computer cards. Data for each of the five senses will be compiled and then sequentially sorted into age, sex, overanxiousness, and anxiety status classes. Nonparametric correlations between the above variables and responses to questions about each sense will be run.

Progress: A questionnaire concerning sensory input towards dental anxiety was given to 100 patients. The results of the questionnaire showed that the sound of the dental drill was the most bothersome sensor, stimuli at the dental clinic. The taste of the anesthetic, feeling of the needle passing through the skin, sight of the needle, and smell of the dental clinic were other bothersome sensory stimuli.

Detail Summary Sheet

Date 24 Sep 82	Prot No.: 82-26	Status: Completed

Title: The Incidence of Maxillary Midline Diastemas in Adults.

Start Date: Jan 82		Est Comp Date: Jun 82
Principal Investigator: Thomas J. McVay, DDS, CPT, DC		Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dentistry		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: To examine the incidence of the maxillary midline diastema with regard to age, sex, and race over five different adult age groups and determine whether the maxillary midline diastema might be age, sex, or race related.

Technical Approach: A random sampling of 5,970 dental records of US Army service members, their dependents, and retirees was reviewed at Fort Gordon, GA. Participation in the study was limited to individuals who possessed all their maxillary anterior teeth, had no history of orthodontic treatment, and possessed no crown or bridge restorations in the maxillary anterior quadrant. Each dental record utilized had to possess a readable x-ray of the maxillary anterior. Each acceptable x-ray was examined for the presence of: a) no diastema, or a diastema of up to 0.49 mm; b) a diastema of between 0.50 mm to 1.49 mm; c) a diastema of over 1.50 mm. The age, sex and race (caucasian, black, oriental) of each participant was noted. Statistical significance was established utilizing the chi-square test.

Progress: Significant results are as follows:

1. A maxillary midline diastema was found in 22.33 percent of the adult population studied.
2. There were no differences in diastema number or size assignable to sex difference.
3. The black race exhibited a greater number and size of diastema than either caucasian or oriental.
4. There were differences in diastema number and size with regard to age, the number decreased with age while the width increased.

Detail Summary Sheet

Date 24 Sep 82	Prot No.: 82-27	Status: Completed

Title: Use of Ultrasonic Vibrations in Endodontics for File Debridement.

Start Date: Jan 82		Est Comp Date: Jun 82
Principal Investigator: Bruce A. Boretsky, DMD, CPT, DC		Facility: DDEAMC
Dept/Svc: Dentistry		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the ability of an ultrasonic cleaning system to debride Hedstrom files used in endodontics.

Technical Approach: 80 Hedstrom files will be used in the following manner:
a. Population #1 - 20 files as received from the manufacturer will be processed as follows: 1) placed in a sterile Baker's sponge for 30 minutes; 2) placed in a E/MC RAI Research Model #250 ultrasonic unit containing 100cc of freshly prepared Cidex and run at 80,000 vibrations/sec for 10 min.; 3) rinsed with 50ml of sterile water; 4) placed in a dry clave (Steele's Model #400) at 320°C for 30 min.; 5) stored in Union Broach endodontic organizer for one hour; and 6) placed in a salt-heat transfer sterilizer at 460°C for 5 seconds.
b. Population #2 - 20 files used on patients not cleaned ultrasonically or sterilized.
c. Population #3 - 20 files used on patients, transferred to the ultrasonic cleaning unit, ultrasonically cleaned, rinsed with sterile water, but not sterilized.
d. Population #4 - 20 files used on patients, ultrasonically cleaned and sterilized according to the regimen mentioned above for population #1.

The po;ulations will be placed on sterile Baker's sponge for temporary storage and transfer to the laboratory where half will be prepared for viewing with the SEM and half prepared for microbiologic evaluation.

Progress: 1. The files from population #1 (new files as received from the manufacturer), population #3 (ultrasonically cleaned) and population #4 (ultrasonically cleaned and dry-claved) were essentially debris free.

2. Files from population #2 (directly from the tooth) were grossly contaminated with debris.

3. Files from populations #1, #3 and #4 were sterile.

4. Files from population #2 demonstrated numerous bacterial colonies.

From this study it is evident that the ultrasonic cleaner is a vital part of the cleaning system. It is both efficient and effective, and eliminates the need for dry-clave sterilization.

Detail Summary Sheet

Date 24 Sep	Prot No.: 82-28	Status: Completed

Title: Herpes, Do Adult Female Patients with Active Genital Herpes Have Concomitant Active Oral Herpes.

Start Date: Jan 82	**Est Comp Date:** Jun 82
Principal Investigator: Steven E. Todd, CPT, DC	**Facility:** DDEAMC
Dept/Svc: Dentistry	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if female patients with active genital herpes have concomitant active oral herpes.

Technical Approach: Patients' past herpes history will be taken, an intraoral and extraoral exam will be given, and a cytological culture will be obtained. The extent of simultaneous active occurrence of oral and genital herpes will be evaluated using a nonparametric correlation (yes-no) and a sign test. Relationships between factors such as age, military status and type of clinical features will be evaluated using an anlysis of covariance and a chi-square frequency distribution prediction.

Progress: Twenty-three subjects were enrolled in this study. Of these 20 reported a past history of recurring oral herpes simplex. Three stated that they could remember only one occurrence of herpes simplex. Eight of the 23 had recurring oral HSV concomitant with genital HSV, two had Type II and six had Type I HSV. All eight noticed prodromal symptoms in both oral and genital locations. This initial study demonstrated a relationship between genital and oral herpes in that adult females may develop active genital and oral lesions concomitantly. The course of recurrent genital herpes is similar to that of recurrent oral herpes. The majority of patients have a prodrome, maximum pain and virus shedding. This study has demonstrated that these two diseases occur concomitantly and that the diagnosis of oral lesions may aid in the diagnosis treatment of patients suffering from genital herpes.

Detail Summary Sheet

Date 24 Sep 82	Prot No.: 82-29	Status: Completed

Title: A Study of the Effect of Dental Anxiety on the Heart Rate and Blood Pressure of the Hypertensive Patient.

Start Date: Jan 82	**Est Comp Date:** June 82
Principal Investigator: Jeffrey W. Wallace, CPT, DC	**Facility:** DDEAMC
Dept/Svc: Dentistry	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To evaluate the cardiovascular responses of the hypertensive patient to stress related to dental treatment.

Technical Approach: Subjects in each of two categories, hypertensive and normotensive, will be tested in terms of blood pressure, heart rate, and anxiety level during four successive dental visits.

Progress: Twenty-eight patients ranging in age from 18 to 45 years in need of routine endodontic treatment were randomly selected for participation. Twelve of these patients had previously been diagnosed as hypertensive, and were designated as the study group. The remaining sixteen had not and they were used as a control. Measurements of blood pressure and heart rate during the course of four dental appointments showed no significant change in spite of different stress situations. Neither was a change in anxiety level noted. Improvements in the methods of study of this subject might provide more expected results.

Detail Summary Sheet

Date 24 Sep 82	Prot No.: 82-30	Status: Completed

Title: Relationship Between the Mesiodistal Width of the Maxillary Central Incisor and Interpupillary Distance.

Start Date: Jan 82	**Est Comp Date:** June 82
Principal Investigator: Vincent A. Cesario, Jr., CPT, DC	**Facility:** DDEAMC
Dept/Svc: Dentistry	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To correlate interpupillary distance to the mesiodistal width of maxillary central incisors as a guide for prosthetic replacement in the edentulous patient.

Technical Approach: All measurements were made with a Boley gauge to the nearest tenth of a millimeter. Interpupillary distances were measured from mid-pupil to mid-pupil, while mesiodistal measurements of the incisor teeth at the widest point. The service members were grouped into the categories white male, white female, black male, and black female--25 in each group.

Progress: 100 US Army service members volunteered to have measurements made of a maxillary central incisor and their interpupillary distance. In three of the four groups studied, the ratios between the mesiodistal width of the maxillary central incisor and the interpupillary distance were statistically similar. The measurements showed consistent relationships for sexual as well as for racial differences. Black male and female subjects had greater measurements than whites, and males were generally larger than females.

Detail Summary Sheet

Date 24 Sep 82	Prot No.: 82-31	Status: Completed

Title: An Evaluation of Age and Sex Determinates From a Panoramic Radiograph.

Start Date: Jan 82	**Est Comp Date:** June 82
Principal Investigator: Terrence S. Murphy, CPT, DC	**Facility:** DDEAMC
Dept/Svc: Dentistry	**Associate Investigators:** Thomas F. Payne, LTC, DC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if age and sex can be accurately estimated from a panoramic radiograph.

Technical Approach: Two hundred panoramic radiographs of acceptable quality were selected from the files fo the Fort Gordon Dental Activity. Twenty radiographs were selected for each five year increment from 18 to 67 years of age. An additional 10 radiographs were selected for a pilot study to insure equal interpretation between the examiners. The examiners discussed criteria during the pilot study but not during the main study. All evaluations were subjective in nature. Radiographs were assigned consecutive numbers from a random numbers table. Each radiograph was projected onto a viewing screen and independently evaluated for age and sex by the PI and an oral pathologist with training in forensic odontology.

Progress: For this study of panoramic x-rays the two examiners were consistent with each other on the estimates of age. Estimated age versus actual age was not as good. While the results may have been statistically significant to a degree, their practical significance is limited. Only about 52% of the estimates were within 5 years($\pm$) of actual age. Sex determination by subjective evaluation of panoramic x-rays proved very inaccurate.

Detail Summary Sheet

Date 27 Sep 82	Prot No.: 82-32	Status: Completed

Title: The Relationship of Tooth Color to Race.

Start Date: Jan 82		Est Comp Date: Jun 82
Principal Investigator: Paul F. Abbey, CPT, DC		Facility: DDEAMC
Dept/Svc: Dentistry		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether any correlation exists between the color of the maxillary central incisor tooth and the race of the individual concerned.

Technical Approach: After a thorough prophylaxis of the maxillary anterior teeth using a rubber cup and prophy paste, tooth color will be obtained of the maxillary central incisor teeth using the Trubyte Bioform (TB) shade guide. The TB values will include the basic range plus five intermediary colors which will be converted to a continuous range from 1 to 13 with 1 being the lightest hue and 13 the darkest. The light source to be utilized will consist of a combination of natural and artificial light. The Spearman Product Moment Correlation Coeffecient will be used to analyze the data in determining the degree of association between tooth color and race.

Progress: Sixty-one dental patients 18 years and older, 35 caucasians and 26 blacks volunteered to participate in this study. The most common TB shade reported for blacks was 59 (converted value 1), while for caucasians it was shade 62 (converted value 2). Chi-square analysis of the data showed no significant difference in tooth color between blacks and caucasians. The Mann-Whitney Rank Sum analysis found both Z_x and Z_y to be within the acceptable ranges, thus the differences in tooth color were due to chance alone and, therefore, not significant. Considering the fact that tooth colors selected were congregated in the lower end of the shade guide, a larger population might produce different results.

Detail Summary Sheet

Date 20 Oct 82	Prot No.: 79-37	Status: Completed

Title: Routine Use of Serum Uric Acid Levels at 36 Weeks Gestation as Screening Test for Preeclampsia as an Aid to Further Management.

Start Date: Jan 80	**Est Comp Date:** Aug 82
Principal Investigator: Paul J. Martin, M.D., CPT, MC	**Facility:** DDEAMC
Dept/Svc: Family Practice	**Associate Investigators:** CPT Ellis M. Knight, MC
Key Words: Serum Uric Acid, Preeclampsia	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results** Mar 82 Continue

Study Objective: To demonstrate that: A. Serum uric acid level is a simple specific screening test for preeclampsia at 36 weeks gestation; B. Its prognostic significance is great enough to warrant its use as a routine lab parameter in all pregnancies. To investigate effects of age and multiparity on serum urate levels.

Technical Approach:

Progress: Twenty-five subjects enrolled through FY 81. Principal investigator ETS'd in Sep 82 without submitting final report.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 81-31	Status: Completed

Title: Use of C-Reactive Protein in Prediction of ARD Prognosis.

Start Date: Jun 80	Est Comp Date: Mar 82
Principal Investigator: David L. Maness, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Family Practice, Medicine, Pathology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: To determine if prospective measurement of C-reactive protein in sera of ARD patients will predict those with significant bacterial infection.

Technical Approach: 100 consecutive ARD patients will have CRP values determined on admission. This will be performed on blood drawn for VDRL and will not require additional needle sticks. In analysis of data, CRP levels at admission will be correlated with antibiotic use, length of hospital stay, peak first day temperature bacterial pathogen isolation, chest x-ray result, clinical diagnosis and virologic diagnosis.

Progress: Total number of subjects enrolled in study: 100. Fifteen patients with adenovirus 21 infection, 3 with Coxsackie B-1, and one with Mycoplasma pneumoniae pharyngitis had no significant difference in admission C-reactive protein and leukocyte counts from 10 patients with group A streptococcal pharyngitis and 9 patients with lobar pneumonia. Admission C-reactive protein and leukocyte count appear to be of no value in discriminating cause of acute respiratory disease in recruits.

Maness DL and Haburchak DR. Admission C-Reactive Protein and Leukocyte Count in Military Recruits with Acute Respiratory Disease. Presented at the National Meeting of the American Society of Microbiology, Mar 82, Atlanta, GA.

Detail Summary Sheet

Date 15 Oct 82	Prot No.: 81-40	Status: Ongoing

Title: The Assessment of Improved Physiologic Function With a Short-Term Exercise Program in Mildly to Moderately Obese People.

Start Date: Oct 82		Est Comp Date:
Principal Investigator: Jeannette South, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To assess whether there is a significant improvement in cardiovascular and pulmonary parameters, with a short-term exercise program in young people (ages 20-40) who are mildly to moderately obese (10-30% above ideal body weight).

Technical Approach: This project involves a graded exercise test during which pulmonary and cardiovascular parameters are monitored. The patient is then placed on either a diet program alone or on a program of both diet and exercise. He/she is also asked to attend weekly nutrition classes. Eight to twelve weeks after beginning the program, the participant is retested to compare pre- and post-study parameters.

Progress: Thirty subjects have undergone the initial graded exercise test. Only 10 patients returned for repeat testing. At least 10 patients have been reassigned or have had serious medical conditions (i.e., pregnancy, MVA) and, therefore, will not be available for followup. Four more are scheduled for followup testing within the next few weeks. Data obtained thus far has been tabulated and a program utilizing the Apple Computer has been written. Hopefully, this program will make it possible to determine whether there has been a statistical improvement in oxygen consumption and mets of work obtained by the participants before and after entering the program.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 82-48	Status: Ongoing

Title: Training Laboratory for Selected Procedure in Emergency Medicine for Family Practice Residents.

Start Date: Aug 82		Est Comp Date:
Principal Investigator: Gerhard J. Hinnen, M.D., MAJ,MC		Facility: DDEAMC
Dept/Svc: Family Practice/Clinical Investigation		Associate Investigators: J. Bruce Arensman, DVM, MAJ, VC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To train Family Practice residents in certain emergency techniques and skills. These include procedures such as tracheostomy, chest tube placement, arterial line placement, venous cutdown, peritoneal lavage, and other procedures a resident may request.

Technical Approach: Using animal models, under general anesthesia, the above procedures are demonstrated by Dr. Arensman and then performed by the residents. All procedures conform to published guidelines and have been approved by the Animal Use and Institutional Review Committees.

Progress: Two residents have gone through this rotation, found it worthwhile, and completed the course successfully. In addition, under the general umbrella of this protocol, many of the above procedures were taught to 13 career dental officers in this command.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 82-56	Status: Ongoing

Title: Sexual Education Inventory.

Start Date:		Est Comp Date:
Principal Investigator: Gary N. Matteson, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop a tool to measure the adequacy of a physician's education in the area of sexual problems.

Technical Approach: Purpose of the study is fourfold: 1) to develop a questionnaire to determine what education background physicians have in sexual education. 2) To determine the prevalence of sexual dysfunctions seen in a Family Practice Clinic. 3) To study the ways physicians deal with patients with sexual dysfunction. 4) To correlate the educational background of the physicians as ascertained on the questionnaire with the reported prevalence of sexual dysfunction seen by the physician.

Progress: Study locally approved in Sep 82, no reportable data available.

Detail Summary Sheet

Date 13 Oct 82 | Prot No.: 78-38 | Status: Ongoing

Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part I. Human Immunologic Reactivity to Fire Ant Antigens. BB IND 1452

Start Date:	**Est Comp Date:**
Principal Investigator: Chester T. Stafford, M.D., COL, MC	**Facility:** DDEAMC
Dept/Svc: Medicine/Immunology, Clinical Investigation	**Associate Investigators:** Robert B. Rhoades, M.D., Medical College of Georgia Charles J. Hannan, Jr., PhD, CPT, MSC
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results** Mar 82 Continue

Study Objective: 1) To compare the skin test reactivity of fire ant venom and its components with whole body extracts (WBE) of fire ants in patients allergic to stings of the imported fire ant. 2) To compare skin test reactivity with in vitro immunologic studies (RAST and Histamine release). 3) To determine the pretreatment immunologic status of fire ant sensitive patients prior to their participation in studies comparing the relative efficacy of immunotherapy with fire ant venom (Part III partocol) versus whole body extracts (Part II protocol) versus placebo; pending DA approval. Part IV on separate summary sheet).

Technical Approach:

Progress: These phases of the study have not begun, pending the completion of Part IV.

Detail Summary Sheet

Date 13 Oct 82	Prot No.: 78-38	Status: Ongoing

Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part IV - In Vitro Testing of Allergenic Substances. BB IND 1452.

Start Date: Aug 79	**Est Comp Date:** Jan 83
Principal Investigator: Chester T. Stafford, M.D., COL, MC	**Facility:** DDEAMC
Dept/Svc: Medicine/Immunology, Clinical Investigation	**Associate Investigators:** Charles J. Hannan, Jr., PhD, CPT, MSC; Robert B. Rhoades, M.D., Medical College of Georgia
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:** $600.00	**Periodic** Mar 82 **Review Results** Continue

Study Objective: Parts I, II and III of this protocol will be conducted under regulations for an Investigational New Drug (IND) and; therefore, production lots of allergens produced at DDEAMC must be subjected to a series of specific evaluations. Tests to be performed include evaluation of: 1) potency, 2) general safety, 3) sterility, and 4) purity as specified in Title 21, Code of Federal Regulations.

Technical Approach:

Progress: FDA approval of our procedure for preparing, and quality control of, the fire ant antigens was recently received and two lots of FE (front end) and AE (abdominal end) antigen have been prepared and are nearly completed in their quality control evaluation. Upon successful evaluation of these products, the precious AQ (venom aqueous phase) will be prepared. We have now collected 620 microliters of whole venom.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 79-34	Status: Terminated

Title: Growth of Human Tumor Stem Cell Colonies in Soft Agar.

Start Date: Jan 80	**Est Comp Date:** May 82
Principal Investigator: James F. Boyd, M.D., LTC, MC	**Facility:** DDEAMC
Dept/Svc: Medicine, Pathology	**Associate Investigators:** Cherry Gaffney, M.D., CPT, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To grow human tumor stem cell colonies in soft agar for the purpose of studying growth kenetics, sensitivity to chemotherapeutic and hormonal agents, and to study estrogen receptors in the cytoplasm of malignant cells by immunofluorescent assay.

Technical Approach:

Progress: No activity during FY 82. Study is terminated due to principal investigator's PCS.

Detail Summary Sheet

Date 22 Oct 82 | Prot No.: 80-14 (WRAMC 7915) | Status: Ongoing

Title: Prevention of Gonadal Damage in Women Treated With Combination Chemotherapy or Radiotherapy Below the Diaphragm for Hodgkin's or Non-Hodgkin's Lymphoma.

Start Date:	**Est Comp Date:**
Principal Investigator: Steven Madden, M.D., MAJ, M.C.	**Facility:** DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To determine whether suppression of gonadal function by oral contraceptives in females will protect these individuals from subsequent damage to the gonads and sterility as a result of radiation therapy or chemotherapy for the treatment of Hodgkin's disease or non-Hodgkin's lymphoma.

Technical Approach: Pre-treatment, the patients will undergo an endocrine evaluation including baseline LH, FSH, prolactin and estradiol along with menstrual history. If possible, ovarian biopsy will be obtained pretreatment. The women will be placed on oral contraceptives. The patients will remain on these agents throughout their therapy and at the completion of chemotherapy and/or radiation therapy, their endocrine evaluation will be repeated. Biopsies will not be repeated.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 80-15 (WRAMC 7810)	Status: Ongoing

Title: Prevention of Gonadal Damage in Men Treated With Combination Chemotherapy/ Radiotherapy for Hodgkin's Disease and Non-Hodgkin's Lymphomas. Addendum #1 to WRAMC Protocol 7810.

Start Date:	Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC	**Facility:** DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To prevent permanent infertility and alterations in normal sexual function caused by combination chemotherapy in the treatment of Hodgkin's disease of histiocytic lymphoma. This is to extend WRAMC Protocol 7810 which was limited to Hodgkin's disease and histiocytic lymphoma.

Technical Approach: To study men ages 18-45 with Hodgkin's disease or non-Hodgkin's lymphoma prior to chemotherapy or infradiaphragmatic irradiation. Patients who have previously received chemotherapy or infradiaphragmatic irradiation will be excluded from this study, as will patients with known history of infertility, chromosomal abnormalities, or prostatic hypertrophy.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 80-28	Status: Ongoing

Title: Antimicrobial Therapy in an Animal Abscess Model.

Start Date: Jun 81	**Est Comp Date:**
Principal Investigator: William L. Moore, Jr., M.D., COL, MC	**Facility:** DDEAMC
Dept/Svc: Medicine, Clinical Investigation	**Associate Investigators:** J. Bruce Arensman, DVM, MAJ, VC Richard W. Harris, CPT, MSC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop an appropriate methodology for examination of effects of antibiotics on monomicrobial and polymicrobial abscesses.

Technical Approach: In order to produce an encapsulated virulent strain, all stock organisms studied will be passed through a mouse or rat by s.c. injection with soft agar. The aspirated organism will then be used for rabbit inoculation.

Progress: A therapy regimen of 40 mg/kg/day of moxalactam was used on New Zealand white rabbits. Whiffle balls were implanted i.p. and four weeks later rabbits were injected with B. fragilis, E. coli or a combination of both organisms. Peak serum levels of 33 mg/ml decreased tenfold in control capsules (implanted wiffle balls) to 3.4 mg/ml. Capsules containing bacteria contained significantly lower amounts of antibiotic than control capsules. Colony counts of monomicrobial and polymicrobial infections was decreased by 2-3 logs, but sterilization was not consistantly obtained. The experiments using moxalactam have been completed and further investigation is now underway using the same technical approach to evaluate metronidazole.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 81-30	Status: Ongoing

Title: In vitro Effect of Cimetidine on Herpes Simplex Virus.

Start Date: Indefinite at present		Est Comp Date:
Principal Investigator: David A. Jordan, M.D., CPT, MC		**Facility:** DDEAMC
Dept/Svc: Medicine		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To determine if cimetidine possesses anti-viral activity in vitro.

Technical Approach: Using two known strains each of HSV I and II placque reduction, assays will be performed using various concentrations on cimetidine in the cell culture median. Appropriate controls will also be run. Results will tehn be determined by the presence or absence of placque reduction in the tubes containing cimetidine. Some idea of antiviral activity in relation to drug concentration will also be gained.

Progress: This project has not been started due to principal investigator's responsibilities as a Resident in the Department of Medicine.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 81-37	Status: Ongoing

Title: Effects of Clostridium difficile Toxin on Ion Transport in Rabbit Ileum and Colon.

Start Date: Sep 81	**Est Comp Date:**
Principal Investigator: William L. Moore, Jr., M.D., COL, MC	**Facility:** DDEAMC
Dept/Svc: Medicine, Clinical Investigation	**Associate Investigators:** J. Bruce Arensman, DVM, MAJ, VC Richard W. Harris, CPT, MSC J.P. Rissing, M.D., VAMC T.B. Buxton, ASCP, VAMC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine ion transport in large and small bowel, and changes due to Clostridium difficile toxin.

Technical Approach: To measure electrolytes in a ligated gut loop and the effect of injection of Clostridium difficile toxin into the solution pumped through the loop.

Progress: The methodology of isolation of rabbit gut loops and perfusion of a balanced electrolyte solution was accomplished. Determinations of normal levels of electrolyte and fluid volume are being performed. Toxin has been isolated and will be used in a perfusion after normal values have been evaluated.

Detail Summary Sheet

Date 22 Sep 82 Prot No.: 81-43 (WRAMC 3168R) Status: Ongoing

Title: Comparison of Modalities for Treatment of SLE Nephritis. Phase I-Split Dose vs Single Daily Dose of SLE Nephritis. Phase II-Chlorambucil Therapy vs Pulse Solumedrol Therapy.

Start Date: Nov 81	**Est Comp Date:**
Principal Investigator: Harold Vonk, M.D., LTC, MC	**Facility:** DDEAMC
Dept/Svc: Medicine/Rheumatology & Nephrology	**Associate Investigators:** Bruce Edwards, M.D., MAJ, MC
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: 1) To evaluate the efficacy and side effects of single daily dose corticosteroids vs split dose steroid therapy. 2) Provide an alternative form of therapy in patients with SLE Nephritis who have not responded to conventional steroids and to evaluate patients clinical and serologic response to therapy.

Technical Approach: After completion at prestudy evaluation, patient is randomized to split dose prednisone vs single daily dose prednisone. Weekly kidney function studies and serologic parameters are obtained. After three months, assessment is made if patient is to go to Phase II of the study or if steroid can be reduced. This is an Army-wide cooperative study.

Progress: Three subjects enrolled to date:

1. Single dose predinosone - Has done well with marked improvement in renal function.
2. Split dose prednisone - Did poorly, dropped from study.
3. Single dose prednisone - Transfer from WRAMC, doing well on reduced steroid dose.

Detail Summary Sheet

Date 21 Oct 82	Prot No.: 81-44	Status: Ongoing

Title: Cardiac Rhythm Disturbances Associated With First Dose Exposure to Doxorubicin.

Start Date: Oct 81		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Cardiology		Associate Investigators: Charles Longer, M.D., MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether persons treated with Doxorubicin (Adriamycin) experience cardiac arrhythmias in the 24 hours after initial exposure.

Technical Approach: Holter monitoring performed 24 hours prior and post patient's first exposure to adriamycin.

Progress: Twenty-five patients have been evaluated, with significant findings of adriamycin induced arrhythmias at the present time.

Detail Summary Sheet

Date 22 Sep 82	Prot No.: 81-45	Status: Terminated

Title: Nifedipine: To Determine Efficacy in the Management of Angina Pectoris IND 9683.

Start Date: Nov 81		Est Comp Date: Jul 82
Principal Investigator: Kenneth D. Week, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the efficacy of nifedipine in the management of angina pectoris; a) where coronary artery spasm may be a pathogenetic element, or b) where fixed obstructive disease is unresponsive to conventional therapy.

Technical Approach: One to twenty-five patients will be treated for at least three months each. Patients with angina pectoris can enter the study if: a) there is clinical electrocardiographic or laboratory suspicion of coronary artery spasm; or b) there is persistent or recurring anginal pain despite maximum conventional therapy.

Progress: A total of 5 subjects were enrolled in this study which has been terminated due to the fact that FDA has released drug for prescription use and ongoing clinical investigation of the drug at this institution has ended.

Detail Summary Sheet

Date 12 Oct 82	Prot No.: 81-46	Status: Ongoing

Title: Programalith-AV

Start Date: May 82	**Est Comp Date:** Mar 83
Principal Investigator: Kenneth D. Weeks, Jr., M.D., MAJ(P), MC	**Facility:** DDEAMC
Dept/Svc: Medicine/Cardiology	**Associate Investigators:** T. Scott Key, M.D., MAJ, MC Robert S. Leverton II, M.D., MAJ, MC John D. Rathbun, M.D., MAJ, MC Joseph J. Cookman, D.O., MAJ, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To establish the efficacy and safety of dual chamber cardiac pacing (A-V sequential).

Technical Approach: as designated in protocol.

Progress: A total of seven (7) patients have agreed to placement of permanent pacemaker generators identified as programalith-AV units. These patients have been closely by means of telepace monitoring and clinic visits. Six of the seven units continue to function at appropriate programmed settings in the DVI mode without evidence of malfunction.

The sole unit operating at other than DVI mode remains functional in the VVI mode. This unit had been programmed to VVI after it was noted that atrium failed to pace; upon chest x-ray, the atrial lead was out-of-position. This unit is fully functional at settings for VVI mode and patient tolerating pacemaker function without deleterious effects.

These patients will be followed at consistent intervals through the Cardiology Clinic, DDEAMC and derived follow-up data forwarded to Pacesetter Systems, Inc.

Further use of this pacemaker for new patient enrollment has been suspended while FDA is evaluating existing data.

Detail Summary Sheet

Date 21 Oct 82	Prot No.: 82-1	Status: Ongoing

Title: SWOG 7924, Multimodal Therapy for Limited Small Cell Carcinoma of the Lung, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To determine the efficacy of sequentially alternating, mutually noncross-resistant, multidrug regimens in remission induction and intensification therapy in patients with limited small cell lung carcinoma. 2) To determine the value of chest radiotherapy added to intensive systemic chemotherapy in reducing chest recurrences, and in improvement of survival. 3) To determine the relative efficacy and toxicity of low-dose, extensive chest radiation when used in close chronologic sequence with systemic multiagent chemotherapeutic regimens. 4) To determine whether radiotherapy ports should be set according to tumor size prior to or after induction chemotherapy. 5) To determine the value of combined systemic chemotherapy and radiotherapy in the control of bulky chest disease.

Technical Approach: Patients with histologically or cytologically proven small cell carcinoma of the lung will be eligible for this study. All patients must have so-called "limited disease". Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 21 Oct 82	Prot No.: 82-2	Status: Ongoing

Title: SWOG 7927/28, Chemotherapy for Multiple Myeloma, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the effectiveness of four different drug combinations for remission induction in previously untreated patients with multiple myeloma. For patients with a 75% tumor reduction, to evaluate the role of 12 months of chemotherapy maintenance with VSP or VSP plus levamisole, when compared with previous experiences.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma will be eligible for this study. Patients should have objective evidence of and be symptomatic from complications due to myeloma. Therapy will follow schema outlined in the protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 82-3	Status: Ongoing

Title: SWOG 7823/24/25/26 ROAP-AdOAP in Acute Leukemia, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazone, vincristine, arabinosyl cytosine, and prednisone) to AdOAP (the same combination using Adriamycin in place of Rubidazone) in adult acute leukemia, as determined by remission rate, remission duration and survival. 2) To determine the comparative toxicity of these regimens. 3) To determine whether late intensification therapy at 9 months after complete remission will improve long-term, disease-free survival. 4) To determine whether immunotherapy using levamisole for 6 months after 12 months of complete remission on chemotherapy improves disease-free survival. 5) To determine the effects of intrathecal Ara-C on the incidence of CNS leukemia. 6) To determine reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia. 7) To study the effects of intensive supportive care in the management of acute leukemia.

Technical Approach: All patients over 15 with a diagnosis of acute leukemia who have not received extensive therapy (defined as more than one course of any other chemotherapeutic agent or combination of agents) will be eligible for this study. The diagnosis of acute leukemia will be made on bone marrow smear, clot section and/or biopsy. An absolute infiltrate of 50% leukemic cells or greater is required.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 23 Oct 82	Prot No.: 82-4	Status: Ongoing

Title: SWOG 8001, Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: 1) To evaluate the effectiveness as determined by the complete remission rate of the L10 protocol using Vincristine, Prednisone and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL. 2) To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-COAP-OPAL. 3) To determine the reproducivility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

Technical Approach: Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria: A) Absolute infiltration of the marrow with >50% blasts; absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100. B) If the absolute infiltrate is 30-49%, evidence of progressive diesease prior to entering the study will be required. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 22 Oct 82 | Prot No.: 82-5 | Status: Ongoing

Title: SWOG 7827, Combined Modality Therapy for Breast Cancer, Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC	Facility:
Dept/Svc: Medicine/Hematology-Oncology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy. 2) To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using one versus two years of combination chemotherapy alone. 3) To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy. 4) To compare the effects of these various adjunctive therapy programs upon the survival patterns of such patients. 5) To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Patients with postoperative radiation therapy are eligible but will be randomized and evaluated separately. Therapy will follow the schema outlined in the protocol.

Progress: One patient entered on study 14 Jan 82, then taken off study 23 Feb 82 because of intolerance to therapy.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 82-6	Status: Ongoing

Title: SWOG 8012, Treatment for Advanced Adenocarcinoma and Large Cell Carcinoma of the Lung: FOMi vs CAP vs FOMi/CAP, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate by pairwise comparison the response-rate, duration of response and survival of 3 regimens FOMi, CAP and FOMi/CAP in patients with advanced (TMN Stage III M_1) adenocarcinoma and large cell undifferentiated carcinoma of the lung. 2) To evaluate the degree of non-cross resistance of FOMi in CAP failures and of CAP on FOMi failures. 3) To compare the toxicities and side effects of FOMi and CAP.

Technical Approach: Patients are eligible who have a histologically confirmed diagnosis of adenocarcinoma of the lung or large cell undifferentiated carcinoma of the lung. All patients must have measurable disease. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 82-7	Status: Ongoing

Title: SWOG 7808, Combined Modality Treatment for Stage III and IV Hodgkin's Disease MOPP #6, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To attempt to increase the complete remission rate induced with MOB-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a partial response at the end of six cycles of MPO-BAP. 2) To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when complete response has been induced with six cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 82-8	Status: Ongoing

Title: SWOG 8027, The Natural History of Pathological Stage $T_{1-2}N_0M_0ER+$ Breast Cancer, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To document recurrence-rates, patterns of recurrence, and survival among patients with Stage I or Stage II node negative ($T_{1-2}N_0M_0$) breast cancer whose tumors are determined to be estrogen receptor positive at the time of surgery.

Technical Approach: All female patients having had a radical, modified radical, or adequate local excision, with axillary node dissection for histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is positive are eligible for this study.

Progress: One patient entered on study, 21 Jul 82. Patient being followed for natural history breast cancer.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 82-9	Status: Ongoing

Title: SWOG 7804, Adjuvant Chemotherapy With 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients With Locally Advanced Gastric Adenocarcinoma, Phase III.

Start Date: Jan 82	**Est Comp Date:**
Principal Investigator: Steven Madden, M.D., MAJ, MC	**Facility:** DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Eligible patients must have localized lesions at least extending into the submucosa and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary, e.g., greater curvature lesion with metastases to superior gastric nodes (Group II) on lesser curvature.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 82-10	Status: Ongoing

Title: SWOG 8006, Preoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx or Larynx, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the length of remission, recurrence-rates, survival-rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs combined therapy utilizing preoperative chemotherapy, surgery and postoperative radiation therapy in operable Stage III or IV eipdermoid carcinoma of the head and neck.

Technical Approach: Patients with operable lesions will be randomized between two therapeutic programs: Arm I - combined therapy including surgery and postoperative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive three courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine and bleomycin.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 82-11	Status: Ongoing

Title: SWOG 7985, Combined Modality Treatment for ER- Breast Cancer, Phase III.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Hematology-Oncology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To compare disease-free interval and survival among control group Stage I (and Stage II node negative) breast cancer patients whose tumors are determined to be ER- at the time of mastectomy, versus Stage I (and Stage II node negative) ER- patients treated with adjuvant CMFV for 6 months. 2) To document recurrence patterns among untreated patients with Stage I breast cancer whose tumors are determined to be ER- at the time of mastectomy.

Technical Approach: All female patients having had a radical, modified radical or ttotal mastectomy, or segmental mastectomy with axillary node dissection for potentially curable, histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is less than 10 femtomoles/mg cytosol protein are eligible for this study. Patients must be registered within 28 days of mastectomy. Patients with previous oophorectomy are eligible provided the oophorectomy was not performed for tumor. Therapy will follow the schema outlined in the protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 22 Oct 82	Prot No.: 82-40	Status: Ongoing

Title: SWOG 7902, Combined Modality Therapy With Chemotherapy, Radiotherapy and Surgery vs Radiotherapy and Surgery in Advanced Previously Untreated (Unresectable) Stage III and IV Epidermoid Cancer of the Head and Neck, Phase III.

Start Date: Jan 82	Est Comp Date:
Principal Investigator: Steven Madden, M.D., MAJ, MC	**Facility:** DDEAMC
Dept/Svc: Medicine/Hematology-Oncology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To compare the survival of Stage II and IV squamous cell carcinoma of the tongue, oral cavity, tonsil, oropharynx, hypopharynx and larynx subjected to radiation therapy followed by surgical excision, if possible, vs survival of patients subjected to chemotherapy with Cis-platinum, Oncovin and Bleomycin (COB), followed by radiation therapy and surgical excision if possible. 2) To determine the incidence and extent of complications arising from chemotherapy and radiotherapy followed by head and neck surgery vs radiotherapy and head and neck surgery.

Technical Approach: Previously untreated patients with a histologically confirmed diagnosis of advanced inoperable squamous cell carcinoma of the head and neck, stages III and IV, of the oral cavity, tongue, tonsil, oropharynx, hypopharynx and larynx are eligible. There must be an evaluable lesion(s). Patients must have a life expectancy of 6 weeks or greater. Therapy will follow schema outlined in the protocol.

Progress: No patients have been entered into this study.

Detail Summary Sheet

Date 13 Oct 82	Prot No.: 82-34	Status: Completed

Title: A Vascular Occlusion Stroke Model: V. The Effect of Thyrotropin-Releasing Hormone (TRH) Therapy.

Start Date: Feb 82		Est Comp Date: Jul 82
Principal Investigator: Angel R. Garcia, M.D., MAJ, MC		**Facility:** DDEAMC
Dept/Svc: Nuclear Medicine, Clinical Investigation		**Associate Investigators:** Charles J. Hannan, Jr., PhD, CPT, MSC
Key Words:		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

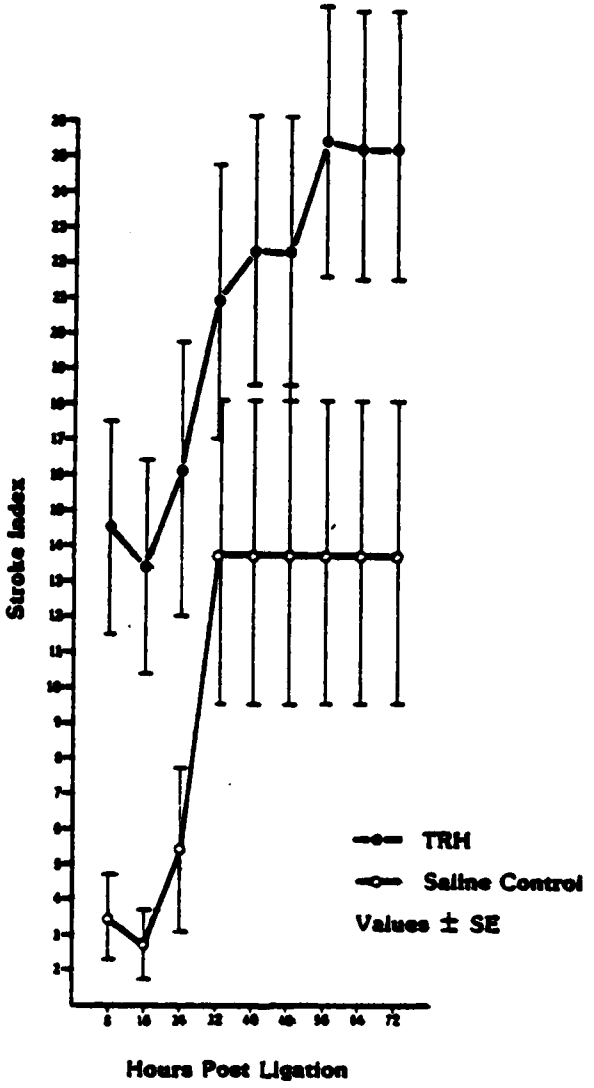
Study Objective: To evaluate the effect of TRH in a model of cerebral ischemia.

Technical Approach: Thirty Meriones unguiculatus, Tum: (MON), maintained on a reversed 12-hour light 12-hour dark cycle, had their left common carotid artery occluded and right common carotid restricted under ketamine anesthesia (50 mg/kg) between 08.30 h and 10.30 h [10]. Immediately after suturing the employed midline incision, either TRH (10 mg/kg, ip in 2 mg/ml sterile saline, Sigma Chemical) or an equal volume of saline was injected alternately in occluded gerbils. Animals were examined at 07.30 h, 16.00 h and 23.00 h and were evaluated neurologically to 72 hours post ligation.

Progress: At the end of one week, the TRH group had 12 (80%) mortalities, whereas the saline control group had 6 (40%). The difference is significant by the chi-square test (P=0.025). The median survival time for the control group was greater than 72 h and for the TRH group as 31 h. The neurological evaluation is summarized in Figure 1 as the mean stroke index at each 8 hour interval. The higher the stroke index, the worse the neurological condition of the animal. A measure of time-to-death (Lee-Desu statistic, P=.0728) and comparison of the stroke indices at the nine observation times (Wald-Wolfowitz Runs Tests, P<.02), also indicated the two groups were different (these nonparametric computer analyses are part of the SPSS Batch System software). One week after occlusion, all surviving animals were fixed by perfusion with Carson's buffered formalin and processed for light microscopy. One of the three survivors in the TRH group and two of the nine survivors in the control group had histologically demonstrated cerebral infarctions. Because of the unexpectedly devastating effect of TRH on the ischemic animals, the possibility of idiosyncratic reaction was considered. TRH in equivalent doses was injected into normal gerbils without unusual effect.

82-34 Continued

Figure 1



Detail Summary Sheet

Date 25 Oct 82	Prot No.: 82-50	Status: Ongoing

Title: Primary Renal Hematuria: A Prospective Evaluation.

Start Date:	Est Comp Date:
Principal Investigator: James A. Hasbargen, M.D., CPT, MC	**Facility:** DDEAMC
Dept/Svc: Medicine/Nephrology	**Associate Investigators:** Mark Anderson, M.D., MAJ, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the etiology and significance of hematuria, microscopic and macroscopic, as well as prognosis in patients who have neither personal or family history of renal disease, nor evidence of systemic disease or extrarenal causes of hematuria.

Technical Approach: Patients studied will be over 18 years of age and will have had either gross or microscopic hematuria (the latter defined as greater than ten red blood cells per high-powered microscopic field), intermittently or continuously for at least a three-month period. This will not include urinary tract hemorrhage, i.e, urinary hematocrit of greater than 3% or clot formation. Historical, physical exam and laboratory criteria must be met prior to the patient's entry into the study, and both the patient and the attending physician must be willing to subject the patient to a comprehensive evaluation in accordance with the protocol to include renal arteriography and renal biopsy if indicated.

Progress: Study locally approved in Aug 82. No reportable data is available yet.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 82-51	Status: Ongoing

Title: IgA Nephropathy: A Prospective Evaluation.

Start Date:		Est Comp Date:
Principal Investigator: James A. Hasbargen, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Medicine/Nephrology,Pathology		Associate Investigators: Mark Anderson, M.D., MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine pathologic and clinical-pathologic criteria for the diagnosis of IgA nephropathy, the prognosis of patients with such a diagnosis and their suitability for continued military service, the extent of evaluation and degree of follow-up required for such patients, and the sensitivity and specificity of various noninvasive diagnostic techniques which potentially could obviate the necessity for renal biopsy.

Technical Approach: Patients studied will be over 18 years of age and will have a renal biopsy proven diagnosis of IgA nephropathy. It is realized that such a diagnosis may be made on the basis of the immunofluorescence finding of glomerular IgA deposition, and that there might be differences of opinion between various pathologists concerning diagnostic criteria for this disease entity. Attending physician and the patient must be willing to submit to a comprehensive evaluation to include long-term follow-up and possibly repeat renal biopsy in accordance with the protocol. Historical, physical exam and laboratory criteria must be met prior to the patient's entry into the study.

Progress: Study locally approved in Aug 82. No reportable data is available yet.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 82-52	Status: Ongoing

Title: Intra-Coronary Streptokinase in Evolving Myocardial Infarction.

Start Date:		Est Comp Date:
Principal Investigator: Joseph J. Cookman, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Medicine/Cardiology		Associate Investigators: Kenneth D. Weeks, Jr, M.D.,MAJ,MC T. Scott Key, M.D., MAJ, MC Robert S. Leverton II, M.D., MAJ,MC John D. Rathbun, M.D., MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To assess the efficacy and safety of intra-coronary streptokinase infusions in patients with acute myocardial infarction.

Technical Approach: Study will be an open label trial in 30 patients with acute myocardial infarction. Within ten hours following onset of acute myocardial infarction streptokinase will be infused directly into the obstructed coronary artery through a coronary angiography catheter. A minimum of 15 patients will be enrolled, with the onset of symptoms to start infusion not exceeding ten hours. The effects of the study drug will be assessed by selective coronary angiography, hemodynamic parameters obtained by right and left heart catheterization.

Progress: Study locally approved in Aug 82. No reportable data is available yet.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 81-36	Status: Completed

Title: The Use of Volume Capacity Determinations of Intermittent Infusion Reservoirs as a Guideline for Maintenance Solution Flushes.

Start Date: Aug 81		Est Comp Date: Jan 82
Principal Investigator: Terry A. Newton, 1LT, ANC		Facility: DDEAMC
Dept/Svc: Nursing/Anesthesia		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1. Determine the volume capacities of the various Intermittent Infusion Reservoirs stocked at DDEAMC.
2. Compare and contrast volume capacities between over-the-needle and winged tipped heparin locks.
3. Determine the amount of heparin flush solution used by nursing personnel in maintaining the patency of heparin locks on a daily basis.
4. Develop nursing guidelines for maintaining heparin locks.

Technical Approach: The data gathered in the first part of the investigation (1 and 2 above) will be used to set guidelines for the maintenance of heparin locks at DDEAMC.

The data collected in the second part of the investigation (3 and 4 above) will be compared to the data collected in the first part and conclusions concerning current practice without guidelines will be made.

Progress: From data collected in this investigation, it is concluded that: 1) There was wide variation in the amount of heparin rinse used to maintain heparin locks at this facility; 2) the amount of heparin rinse used with each flush varied with the type of heparin lock in place; 3) the over-the-needle heparin locks were used in greater frequency than the winged tipped catheters during the data collection period; 4) the volume capacities of commercially prepared heparin locks were of a smaller amount thant the converted heparin locks of the same catheter type; 5) there was a lack of documentation with respect to the type of heparin lock in place, the gauge of the catheter, and the amount of heparin rinse to be used with each flushing procedure during the investigation period.

The data collected did not: 1) reflect the purpose of the flushing procedure; 2) enumerate how many heparin locks were in place on a daily basis; 3) indicate from which nursing unit the data was collected (this was done purposefully to insure anonymity); 3) reflect the rationale for using the amounts of flush used by nursing personnel, and did not explain how the personnel arrived at a particular amount as being "enough" without having empirical data to support their decision.

The investigator recommends a future study to determine the validity of the major assumption of this study used in the hypothesis testing that the amount of heparin rinse needed to maintain the patency of a heparin lock is twice the volume capacity of the heparin lock. From the literature reviewed, it is evident that some facilities

may be using volume capacity as a guide to determine the needed amount of heparin rinse based on catheter type.

The investigator recommends that documentation should be made on the DA Form 4678 as to how much maintenance solution should be used with each flush procedure. Once there is available empirical data to support a recommended amount, which may be best reflected as a ratio of heparin rinse to heparin lock volume capacity; this amount may be approved by a Therapeutic Agents Board and reflected in a Nursing Standard Operating Procedure composed by a Nursing Standardization Committee.

As a whole, this study demonstrated the variety of volume capacities of the various heparin locks in use at one health care facility and the need for standardizing the amount of the heparin rinse needed to maintain the heparin lock's patency. As nursing is a science which utilizes the scientific method in obtaining empirical data to support its practice, procedures within the realm of nursing must be based on such sound data rather than on intuition or arbitrary opinions.

Detail Summary Sheet

Date 22 Sep 82	Prot No.: 81-41	Status: Completed

Title: The Relationship of Job Satisfaction and Empathic Ability Among Hospital Staff Registered Nurses.

Start Date: Oct 81	**Est Comp Date:** Mar 82
Principal Investigator: Cathy J. Johnson, CPT, ANC	**Facility:** DDEAMC
Dept/Svc: Nursing	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To examine the relationship of job satisfaction and empathic ability among staff nurses working in a hospital setting.

Technical Approach: Participants were asked to complete two questionnaires. One questionnaire evaluated empathic ability and the other measured degree of job satisfaction. The two questionnaires were attached together and given out as one handout item. Comparisons were made of empathic abilities between nurses experiencing high degrees of job satisfaction and nurses experiencing low degrees of job satisfaction.

Progress: Study was completed in March 1982. Findings are as follows: Staff nurses gave more high level empathic responses than low level empathic responses and were moderately satisfied with their jobs. Differences in responses to stress-laden situations and job satisfaction were found among nursing specialties. Pearson correlation coefficients computed for the relationship of job satisfaction and empathic ability did not support a significant relationship between the two variables of job satisfaction and empathic ability.

Detail Summary Sheet

Date 27 Sep 82	Prot No.: 82-14	Status: Ongoing

Title: Inpatient Nursing Care Satisfaction Survey.

Start Date: Dec 81		**Est Comp Date:** Dec 82
Principal Investigator: Allan E. Shapiro, LTC, ANC		**Facility:** DDEAMC
Dept/Svc: Nursing		**Associate Investigators:** Richard A. Sherman, PhD, CPT, MSC
Key Words: Inpatient satisfaction Hospital Nursing		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To determine adult inpatient satisfaction with their nursing care at DDEAMC.

Technical Approach: Distribute anonymous response survey to all inpatients on participating wards when they receive their discharge orders. Collect sufficient surveys from each ward so that a sufficient number are collected from each to be representative of its population.

Progress: All data has been collected and reduced to computer readable format. Computer analysis of the data is in progress.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 82-16	Status: Completed

Title: The Relationship Between Time and Functional Residual Capacity in Normal Healthy Subjects Assuming the Supine Position.

Start Date: Dec 81		Est Comp Date: Sep 82
Principal Investigator: Jaye P. Feltz, CPT, ANC		**Facility:** DDEAMC
Dept/Svc: Nursing/Anesthesiology		**Associate Investigators:** Gary A. Miller, CPT, ANC Benjamin Mills, CPT, ANC
Key Words:		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To determine if there is a measurable relationship between varying time intervals and FRC in normal, healthy subjects assuming the supine position.

Technical Approach: From a volunteer sample, the subjects were placed in an experimental or a control group. The subjects were randomly assigned to the groups using a table of random digits. The FRC was measured with a Hewlett-Packard Model 47804A/47804S Pulmonary Calculator System utilizing the multiple breath nitrogen clearance method. On the experimental group, the subject was placed in the supine position and the FRC was measured at zero, thirty, and sixty minutes. In the control group, the FRC was measured in the supine position on three occasions 30 minutes apart, however, the subject did not remain supine between the measurements. The data were analyzed by a nested analysis of variance with a level of significance of $p=0.05$.

Progress: The overall finding of this study was that the mean actual change from baseline in FRC at 30 minutes in the supine position in the experimental group was -0.225 liters while in the control group the mean change in FRC was only 0.014 liters. However, at 60 minutes in the supine position, the difference between groups was not great. The mean actual change in the experimental group at 60 minutes was -0.100 liters while in the control group the mean change in FRC was -0.038 liters. There was no significant statistical difference between the two groups at either 30 or 60 minutes in the supine position. Even though there is no significant statistical difference in FRC between groups, there may be a clinical significance. At 30 minutes in the supine position, the mean actual and percent changes from baseline in the experimental group followed a downward trend while these values slightly increased in the control group. However, the investigators feel that the rudimentary difference between the groups at 60 minutes in the supine position would bear no clinical significance.

Detail Summary Sheet

Date 26 Oct 82	Prot No.: 82-17	Status: Ongoing

Title: The Effects of Anesthetic Gases and Vapors on Pulmonary Surfactant Surface Tension.

Start Date: Dec 81	**Est Comp Date:** Dec 82
Principal Investigator: Raymond W. Griffith, CPT, ANC	**Facility:** DDEAMC
Dept/Svc: Nursing/Anesthesiology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if gases and vapors routinely used in the clinical practice of anesthesia interfere with the surface active capability of pulmonary surfactant.

Technical Approach: Washings from human lungs were obtained at autopsy and the surfactant was purified utilizing the Folch procedure, after lyophilization of the specimen. The surfactant was then floated on saline and a DuNruy surface tension meter was used to measure surface tension during exposure to varying concentrations of oxygen, nitroprusside, and halothane.

Progress: Project is completed. Data is currently being analyzed and a final report of findings will be completed by November 30, 1982.

AD-A121 980 CLINICAL INVESTIGATION PROGRAM REPORT CONTROL SYMBOL MED 300(U) DWIGHT DAVID EISENHOWER ARMY MEDICAL CENTER FORT GORDON GA DEPT OF CLINICAL INVESTIGATION 2/2

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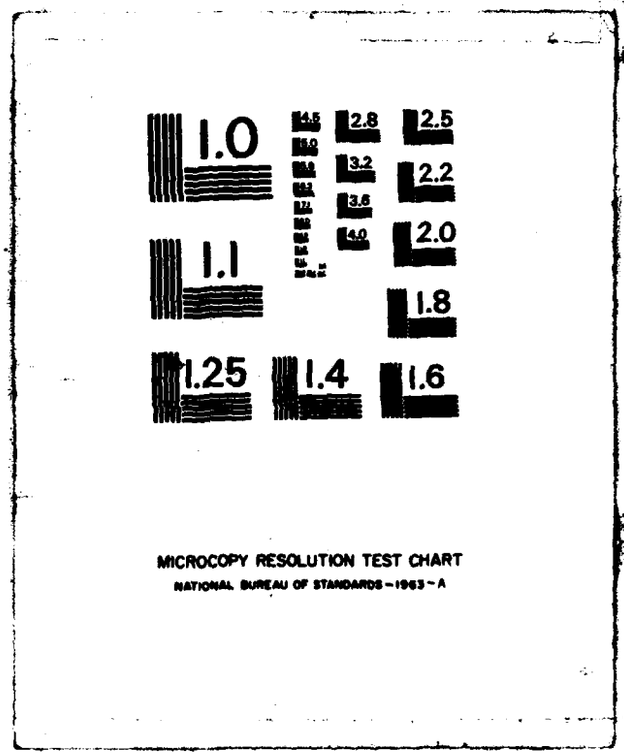
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Detail Summary Sheet

Date 12 Oct 82	Prot No.: 82-21	Status: Completed

Title: The Current Status of Thumbsucking and Related Behaviors.

Start Date: Dec 81		Est Comp Date: Jun 82
Principal Investigator: Janice Nelson, LTC, ANC		Facility: DDEAMC
Dept/Svc: Nursing		Associate Investigators: Cynthia Moen-Nogueras, MAJ, ANC Larry E. Wilson, CPT, ANC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To gain descriptive information concerning thumbsucking, security seeking and feeding behaviors of children that would be useful in advising and counselling parents.

Technical Approach: 1500 questionnaires were made available to parents utilizing the inpatient and/or outpatient facilities at DDEAMC, WRAMC, Ft Meade, MD, Ft Belvoir, VA, and numerous civilian day care centers in the Washington, D.C. area. 816 completed questionnaires were returned. Tabulated data has been analyzed using descriptive statistics, chi-square and t-tests; .05 level of significance was required. Variables were analyzed regarding these groups in the total sample: Thumbsuckers vs non-thumbsuckers; military dependents vs civilian dependents as appropriate.

Progress: Some data is being reanalyzed, but the following conclusions can be made: 1) Pacifier users tended not to suck thumbs. Pacifier users who did thumbsuck had stopped use of pacifier at younger age and had stopped of own accord. 2) Children who were thumbsuckers were more apt to have security object (favorite: blanket with satin edge). 3) More children who were not thumbsuckers are in high weight category at present. (No significant difference at birth). 4) Children who were thumbsuckers began attending day care at earlier age than non-thumbsuckers. 5) Parents found most effective cure for thumbsucking was to do nothing. Other data is available and will be furnished in the formal presentation of the study. DDEAMC is one of the multiple data collection agencies. LTC Janet Southby, ANC, WRAMC and LTC Kathryn Ammon, ANC, Ret., Catholic University of America are the principal investigators for the study.

Detail Summary Sheet

Date 12 Oct 82	Prot No.: 82-45	Status: Ongoing

Title: Ambulatory Surgery Research Program.

Start Date: Jul 82		Est Comp Date:
Principal Investigator: Bonnie Jennings, MAJ, ANC		Facility: DDEAMC
Dept/Svc: Nursing		Associate Investigators: Richard A. Sherman, PhD, CPT, MSC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To gather data on agreeable subjects for the first three years of the program's existence to evaluate program and modify as indicated. To assess efficacy of patient education. To evaluate various educational and surgical modifications (i.e., presurgical relaxation training effects postoperatively).

Technical Approach: Use of questionnaires preoperatively, on day of surgery, and after discharge. Patient education preoperatively via pamphlet, one on one teaching, and postoperatively before discharge. Once a stable population is identified, employ presurgical relaxation tapes.

Progress: 14 subjects enrolled to date, no reportable data available.

Detail Summary Sheet

Date 22 Sep 82	Prot No.: 82-49	Status: Ongoing

Title: The Use of Social Support by Rheumatoid Arthritic Women from Different Cultural/Ethnic Backgrounds.

Start Date: Sep 82	**Est Comp Date:** Sep 84
Principal Investigator: Vickie A. Lambert, RN, D.N.Sc.	**Facility:** DDEAMC/Medical College of GA
Dept/Svc: Nursing	**Associate Investigators:** Clinton E. Lambert, Jr., CPT, ANC
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To identify differences in the nature of the relationships between three (3) types of social support and psychological well-being in rheumatoid arthritic women from three (3) different cultural/ethnic backgrounds.

Technical Approach: Administration of three structured questionnaires by way of interview. Interview to be conducted while subject waiting for scheduled clinic appointment with rheumatologist.

Progress: Study just started, no reportable data available yet.

Detail Summary Sheet

Date 22 Sep 82	Prot No.: 80-23	Status: Terminated

Title: Evaluation Study on Sulfamethoxazole-Trimethoprim Lactate in 5% Sheep Blood Agar Plate. (Children)

Start Date: Oct 80		Est Comp Date:
Principal Investigator: Charles L. Lemke, LTC, MSC		Facility: DDEAMC
Dept/Svc: Pathology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: To evaluate the percentage of beta hemolytic streptococci isolated from a normal pediatric population utilizing the standard procedures versus the use of the selective SXT media.

Technical Approach: Approximately 100 normal pediatric patients will be utilized in this study and the results will be evaluated.

Progress: Administratively terminated due to inactivity for the past two years.

Detail Summary Sheet

Date 3 Nov 82	Prot No.: 81-20	Status: Ongoing

Title: Steroid Receptor Status of Cells Grown in Tissue Culture Started From Human Malignant Stem Cells.

Start Date: Apr 81	**Est Comp Date:** Mar 83
Principal Investigator: Cherry L. Gaffney, M.D., CPT, MC	**Facility:** DDEAMC
Dept/Svc: Pathology, Medicine, Clinical Investigation	**Associate Investigators:** James C. McPherson III, Phd, DAC Robert W. Prior, MT, DAC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To establish clones from individual malignant stem cells, preferably from breast cancers, and to determine estrogen and progesterone receptor status of numerous clones as well as the individual cells within the clones.

Technical Approach: Harvesting cells from malignant effusions, separating out the tumor cells, and planting the tumor cells in semi-solid cell culture. Estrogen and progesterone receptor status will be determined by a fluorescent stain recently marketed by Zeus which we are investigating in Protocol 81-21.

Progress: Due to the death of the patient who had had periodic malignant effusions, no samples have been processed recently. If an appropriate patient presents for treatment, attempts for culture will be renewed according to protocol. Results from 70 cases from DDEAMC and University Hospital have been recorded and are currently under review for statistical correlation with Cytosol values. Estimated date of completion is March 1983.

Detail Summary Sheet

Date 3 Nov 82	Prot No.: 81-21	Status: Ongoing

Title: An Evaluation of the Fluorescent Cytochemical Detection of Steroid Receptor Positive and Negative Cells in Human Breast Carcinoma.

Start Date: May 81		Est Comp Date:
Principal Investigator: Cherry L. Gaffney, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Pathology		Associate Investigators: Janet Riggsbee, MT
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: There is a new method of determining estrogen and progesterone receptor (ER-PR) status of tissue by use of fluorescent cytochemistry. We are using Zeus Chemicals' newly marketed "Fluorocep" stain. Our study is designed to evaluate our correlation between Fluorocep staining results and the conventional cytosol method results. We are also evaluating reproducibility of results.

Technical Approach: All malignant breast tumors biopsied in our hospital are being evaluated by Fluorocep staining for estrogen and progesterone receptors on the diagnostic frozen section and on a portion of the tissue that is sent to Upjohn for cytosol ER-PR determination. Results will be correlated after sufficient specimens have been evaluated. Unstained frozen sections of breast biopsies are being exchanged with a pathologist at University Hospital, Augusta, GA for Fluorocep staining by both of our labs and results are being exchanged. Results will be correlated after sufficient specimens have been evaluated.

Progress: A procedure has been established and is in current practice in the Anatomic Pathology Section for routine submission of tissue from breast biopsies to our Serology Section for staining.

Detail Summary Sheet

Date 3 Nov 82	Prot No.: 81-22	Status: Ongoing

Title: Immunopathological Identification (Classification) of Lymphomas.

Start Date: Nov 81		Est Comp Date:
Principal Investigator: Mark C. Anderson, D.O., CPT, MC		Facility: DDEAMC
Dept/Svc: Pathology		Associate Investigators: Janet Riggsbee, MT, ASCP, DAC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop an aid in the diagnosis and evaluation of human lymphomas for routine use on biopsy specimens.

Technical Approach: Old cases, using paraffin sections will be studied first to evaluate the immunofluorescent technique. From all biopsy lymphnode material, a sampling will be snap-frozen and stored at -70°C. Immunofluorescent testing with various antisera will be performed on each biopsy and results recorded by technologist and analyzed by pathologist. Correlation of other histological procedures and data and resulting diagnosis is the responsibility of the pathologist.

Progress: Evaluating peroxidase methods in addition to immunofluorescent methods and experimenting with routine fixatives.

Detail Summary Sheet

Date 12 Oct 82	Prot No.: 81-32	Status: Ongoing

Title: A Comparative Study of Immunofluorescence in Fresh Frozen and Paraffin-Embedded Skin Tissue.

Start Date: Jun 81		Est Comp Date:
Principal Investigator: Janet H. Riggsbee, MT, DAC		Facility: DDEAMC
Dept/Svc: Pathology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: To confirm the results of previous investigators, to develop a reliable technique for the processing of paraffin-embedded skin tissue, and to investigate the demonstration of complement deposits in paraffin-embedded skin tissue of patients with certain auto-immune skin disorders.

Technical Approach: In patients suspected of having auto-immune disease, biopsies are routinely taken for immunofluorescent studies and H&E sections. Some of the remaining paraffin-embedded tissue will be processed according to various methods that we establish and stained by immunofluorescence antisera.

Progress: Six cases have been appropriate for study. Of these six, three were found to have no deposits. The remaining three demonstrated some deposits, although not as diagnostically complete as the frozen tissue. This inconsistency may be due to the many factors involved in using formalin fixed, paraffin-embedded tissue. A limited number of samples has been appropriate for study and, therefore, no definite conclusions can be drawn at present.

Detail Summary Sheet

Date 3 Nov 82	Prot No.: 81-33	Status: Ongoing

Title: Evaluation of the Roche Laboratory Isomune LD-1 and Isomune CK-MB Test Kits as Compared to the Helena Laboratories CPK, LDH Isoenzyme Techniques in the Diagnosis of Acute Myocardial Infarction

Start Date: Jul 81		Est Comp Date:
Principal Investigator: Mark C. Anderson, D.O., CPT, MC		**Facility:** DDEAMC
Dept/Svc: Pathology		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: A comparison of the Helena and Roche methods of isoenzyme analysis to ascertain the following: a) Ability of each test to discriminate between disease and non-disease states; b) time required for diagnostic profile completion for each methodology.

Technical Approach: Perform routine isoenzyme (Helena methodology) analysis on all patients admitted to MICU for chest pain. Select 25 patients having diagnostic criteria for acute myocardial infarction and choose 25 people admitted for chest pain, but lacking EKG changes and having no evidence of enzyme elevations. On these 50 patients perform the Roche CPK-MB and LDH-1 tests on their routine specimens. This population will be used to make the analysis described in the objectives above.

Progress: Have experimented with methodology, are awaiting significant numbers of test runs to evaluate test applicability.

Detail Summary Sheet

Date: 20 Oct 82	Prot No.: 81-35	Status: Terminated

Title: Comparative Study of API-20E, Micro-Scan and Micro-ID Methods of Identification of Enterobacteriaceae.

Start Date: Oct 81		Est Comp Date: Sep 82
Principal Investigator: Pablo M.R. Lomangcolob, M.D., MAJ, MC		Facility: DDEAMC
Dept/Svc: Pathology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: To determine the best suitable method to use at DDEAMC for the identification of Enterobacteriaceae by comparing cost and accuracy of API-20E, Micro-Scan and Micro-ID methods.

Technical Approach:

Progress: Administratively terminated. Principal investigator PCS'd without submitting a report.

Detail Summary Sheet

Date 20 Oct 82	**Prot No.:** 82-33	**Status:** Ongoing

Title: Training Laboratory for Neonatal Procedures.

Start Date:	**Est Comp Date:**
Principal Investigator: John B. Woodall, M.D., LTC(P), MC	**Facility:** DDEAMC
Dept/Svc: Pediatrics	**Associate Investigators:** Steven Larson, M.D., LTC, MC J. Bruce Arensman, DVM, MAJ, VC
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To familiarize residents on rotation through the Department of Pediatrics with some emergency procedures in the newborn. Initially, these will be: a) endotracheal intubation; b) thoracentesis for pneumothorax and placement of chest tube; c) umbilical vein and artery catheterization.

Technical Approach: One-half day each month will be scheduled for the residents on rotation in the Department of Pediatrics to receive the proposed training.

Progress: To date time schedules have not permitted starting the program.

Detail Summary Sheet

Date 3 Nov 82	Prot No.: 82-19	Status: Completed

Title: Health Needs Assessment of A.I.T. Students: A Pilot Project.

Start Date: Oct 82	**Est Comp Date:** Feb 82
Principal Investigator: Pablo J. Nogueras, M.D., COL, MC	**Facility:** DDEAMC
Dept/Svc: Preventive Medicine Activity	**Associate Investigators:** Carole Gorman, COL, ANC
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: 1) To test a health assessment needs questionnaire, and 2) to provide practical experience in interview techniques to selected nursing students of the Medical College of Georgia.

Technical Approach: The investigators will supervise two groups of student nurses who will interview 90 patients athe the TMC's. The method of interview as well as any problems with the questionnaire as a tool will be discussed. The student nurses will then supervise the completion of the questionnaire by 450 students from selected A.I.T. classes.

Progress: Project completed, data is being analyzed.

Detail Summary Sheet

Date 22 Sep 82	Prot No.: 80-11	Status: Terminated

Title: Increasing Hypertensive Regimen Compliance by Teaching Doctor-Patient Negotiations.

Start Date: Feb 80		Est Comp Date:
Principal Investigator: William G. Bissell, M.D., LTC, MC		Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Jul 82 Terminate

Study Objective: To a-tempt to develop a cost-effective method of improving hypertensive regimen compliance by utilizing a videotape presentation to teach both doctors and patients better methods of communication.

Technical Approach: A videotape has been produced that shows typical doctor-patient interactions and then specific ways in which the doctor and the patient can facilitate better communications. This tape will be shown to groups of Family Practice patients who are being treated for hypertension and to their Family Practice physicians. Some groups will have a group discussion after the film, others will not. Together with control groups, a three by three study will be done with nine groups of patients. Parameters such as systolic and dyastolic B.P., body weight, and amount of medication will be analyzed for all groups.

Progress: Administratively terminated due to lack of progress.

Detail Summary Sheet

Date 22 Sep 82	Prot No.: 80-12	Status: Terminated

Title: Development of a Scale to Predict Trainee Failure in the Army.

Start Date: Feb 80	**Est Comp Date:**
Principal Investigator: William G. Bissell, M.D., LTC, MC	**Facility:** DDEAMC
Dept/Svc: Psychiatry & Neurology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results** Jul 82 Terminate

Study Objective: To develop a cost-effective, easily administered screening examination to identify those trainees who will subsequently not be able to complete training due to emotional immaturity.

Technical Approach: A set of 148 questions has been developed which assesses specific ego functions which are necessary to successfully complete military training. Deviation from normal scores is hypothesized to be predictive of subsequent failure.

Progress: Administratively terminated due to lack of progress.

Detail Summary Sheet

Date 3 Nov 82	Prot No.: 81-15	Status: Completed

Title: The Impact of Individual Counseling Reorganization in an Inpatient Psychiatric Melieu.

Start Date: Feb 81	**Est Comp Date:**
Principal Investigator: Charles S. Burke, M.D., CPT, MC	**Facility:** DDEAMC
Dept/Svc: Psychiatry & Neurology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results** Mar 82 Continue

Study Objective: a) To study the effect that different requirements for individual counseling would have on the attitudes of patient groups. b) Assess the impact the different approaches would have on staff performance.

Technical Approach: The project was scheduled to study a six-month period of time on three wards consisting of five teams: three control, two experimental. The Ward Atmosphere Scale (WAS) was used to assess patient and staff attitudes, twice prior to the implementation of the new counseling requirements on the experimental wards and four times afterwards.

Progress: The investigation has been completed with data collection, statistical analysis and review complete. Preliminary statistics evaluation has failed to demonstrate any statistical differences. However, some promising trends are suggested which may merit further study.

Detail Summary Sheet

Date 14 Oct 82 Prot No.: 81-34 Status: Ongoing

Title: Dexamethasone Suppression Test (DST) in Depression: Clinical and Psychological Correlates and Response to Tricyclic Antidepressants (TCA).

Start Date: Jul 81	Est Comp Date:
Principal Investigator: Andrea C. Bradford, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jul 82 Review Results Continue

Study Objective: 1) Test efficacy of DST in diagnosing major depression; 2) determine whether there are a subset of patients with cortisol hypersecretion and normal DST; 3) determine whether or not there are correlates in family history, psychological test results or response to desipramine or amitriptyline to hypersecretion of cortisol, response to DST or timing of escape from cortisol suppression; 4) Determine whether or not cortisol hypersecretion and abnormal DST correct on recovery.

Technical Approach: 1) Baseline 24-hour urine for free cortisol, 0800 and 2300 serum cortisol, psychological testing, depression scales, family history; 2) 1 mg dexamethasone at 2300 followed by 0800, 1600, and 2300 serum cortisols; 3) treatment with tricyclic desipramine or amitriptyline (double-blind) daily depression checklist, weekly depression scales; 4) after four weeks, or upon clinical remission of depression, repeat baseline studies.

Progress: Six subjects enrolled in study as written during 1981-82. Request extension for re-write of protocol and re-submission due to technical difficulties encountered in acquiring subjects with double blind design, limited types of antidepressants used, and difficulty in diagnosing without results of DST available to the physician,

Detail Summary Sheet

Date 14 Oct 82	Prot No.: 82-12	Status: Completed

Title: Racial Variations on the MacAndrew Alcoholism Scale of the Minnesota Multiphasic Personality Inventory (MMPI).

Start Date: Oct 81	Est Comp Date: Aug 82
Principal Investigator: Glenn D. Walters, PhD, CPT, MSC	Facility: DDEAMC
Dept/Svc: Psychiatry & Neurology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To investigate the effects of race on the MacAndrew Alcoholism Scale (MAC) of the MMPI. Based on past research, it seems feasible that the MAC should discriminate between alcoholics and nonalcoholics in both black and white patient samples. However, the usefulness of the MAC with black patients cannot be taken for granted since nonwhite subjects were grossly under-represented in MacAndrew's original sample.

Technical Approach: DDEAMC patients consisted of 70 (35 black, 35 white) male psychiatric inpatients administered the MMPI as part of the routine diagnostic/treatment process. A power analysis revealed that a cell size of 20 subjects was sufficient to achieve an effect. However, it was felt that a more conservative cell size of 30-35 would yield even more powerful results. The following criteria define which psychiatric inpatients were included in the study: a) must be between the ages of 20 and 45; b) must be male; c) no history of serious alcohol or drug abuse; d) no evidence of any organic disorder. Research Design: Two independent variables, race (black, white) and abuse status (alcoholic, nonalcoholic) was varied by means of a 2x2 factorial design in order to determine their effect on the dependent measure, group average MAC scores. The Mac's discriminative power (alcoholic-nonalcoholic) and association with various behavioral/personality correlates was compared across racial conditions.

Progress: The current data indicate that while black and white alcoholics in an active duty military sample do not differ significantly on the MAC (both in terms of mean MAC scores and accurate identification by means of cutting scores), the MAC was able to discriminate between white alcoholics and nonalcoholics. The inability of the MAC to discriminate between black alcoholics and nonalcoholics appeared to be the result of the high scores achieved by black nonalcoholics and suggests that the MAC may not be as useful in detecting substance abuse in blacks as it is in whites in this sample. It is concluded, therefore, that clinically significant black-white differences were observed on the MAC in an active duty military sample. Nevertheless, further research is necessary in order to document, evaluated, and explore this effect and its generalizability.

Detail Summary Sheet

Date 14 Oct 82	Prot No.: 82-42	Status: Completed

Title: Behavioral and Personality Correlates of Psychiatric Patients With DSM III Diagnoses of Schizophrenia and Schizophreniform Disorder.

Start Date: May 82	**Est Comp Date:** Aug 82
Principal Investigator: Glenn D. Walters, PhD, CPT, MSC	**Facility:** DDEAMC
Dept/Svc: Psychiatry & Neurology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To investigate the behavioral and personality (Minnesota Multiphasic Personality Inventory: MMPI) correlates of two DSM III diagnostic categories, schizophrenia and schizophreniform disorder. A related purpose for doing this research is to use the background literature search as the basis for a review article on the MMPI as applied to schizophrenia, an area of research in need of integration.

Technical Approach: Subjects for this study will be approximately 250 (75 schizophrenics, 75 schizophreniform disorders, 100 psychiatric controls) male psychiatric inpatients administered the MMPI as part of the routine diagnostic/treatment process. The criterion diagnoses will be established by a psychiatry resident or staff working on one of the DDEAMC inpatient wards (12 &13) using DSM III guidelines. In most cases patients will have been diagnosed on two separate occasions, by two different psychiatrists/residents. This information will be used to calculate inter-rater agreement for diagnosis. When two competing diagnoses are offered, the more recent will be used as the criterion diagnosis. The following define which psychiatric inpatients will be included in this study: 1) Must be between the ages of 18 and 55. 2) Must be active duty. 3) Must be male. 4) No evidence of any clear organic disorder (CAT scan, neuro-psch). 5) Omitted fewer than 30 items on the MMPI.

Progress: 131 active duty males were studied. The results of the present study indicate that schizophrenic and schizophreniform patients, while sharing a relatively large number of behavioral and demographic features in common, differ in several important ways, to include degree of disturbance, premorbid adjustment, chronicity, ability to recompensate, and possibly even genetic predisposition to the development of psychopathology. Whether schizophreniform disorder is a less severe/chronic variant of schizophrenia, or a separate, but related, disorder is a question which requires further investigation. Utilizing additional personality measures (e.g., Rorschach), more sophisticated approaches to determine family psychopathology, and estimates of premorbid adjustment, response to treatment, and long-term outcome may shed greater light on these issues.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 82-55	Status: Ongoing

Title: Relative Accuracy of Adolescent- and Adult-Normed MMPI Profiles in Young Enlisted Military Personnel.

Start Date:	**Est Comp Date:**
Principal Investigator: Jerry R. DeVore, PhD, CPT, MSC	**Facility:** DDEAMC
Dept/Svc: Psychiatry/Psychology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative CMA Cost:**	**Periodic Review Results**

Study Objective: To investigate the relative accuracy of behavioral narratives generated by adolescent- and adult-normed MMPI profiles.

Technical Approach: Three hypotheses will be tested in this study: 1) behavioral narratives based on adolescent MMPI norms will be rated as reasonably accurate by a group of interviewers familiar with the behavior of the subjects under investigation (i.e., active duty enlisted personnel between the ages of 18 and 21); 2) behavioral narratives based on adolescent MMPI norms will be judged as more accurate than narratives generated by K-corrected or non-K-corrected adult norms; 3) various patient characteristics (e.g., race, sex, education) will not have a major impact on the results.

Progress: Study locally approved in Sep 82, not yet implemented.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 82-35	Status: Completed

Title: A Demographic Profile of Spouse Abuse Cases Referred to Social Work Services, DDEAMC.

Start Date: Jan 82	Est Comp Date: Mar 82
Principal Investigator: Nelufar Mariam Tabatabai, Graduate Student	Facility: DDEAMC
Dept/Svc: Social Work Service	Associate Investigators: Ronald J. Platte, PhD, LTC, MSC
Key Words: Spouse abuse	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To develop a demographic profile of spouse abuse cases referred to the Social Work Service at DDEAMC.

Technical Approach: This study utilized a retrospective record review method correlating certain demographic and descriptive variables with the dynamics involved in spouse abuse cases reported to this medical center.

Progress: There were 77 closed spouse abuse cases extending over a five year period, Jan 77 through Dec 81, that were reviewed for this study. The majority of the abusive husbands and battered wives from this population sample fell between the 21-25 year old age range. The model response for number of years married was between 1-5 years. Most of the couples involved in the spouse abusing pattern had one child 5 years old or younger. The majority of both husbands and wives had achieved a 12th grade level or high school education. Almost one-half of the abusive husbands fell between the 35-38 rank. Over three-fourths of the couples were of homogeneous ethnic composition. Research, such as this study, serves two functions. First is that the social worker is afforded therapeutic tools and crucial information to utilize as he or she works with the spouse abuse case. The second is that research usually generates more research. Further research on spouse abuse could prove invaluable in making the public aware of this epidemic, as well as helping those working with these cases deal more effectively with this complex phenomenon as more information, insight and understanding is generated.

Detail Summary Sheet

Date 3 Nov 82	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: May 78	**Est Comp Date:**
Principal Investigator: John E. Riffle, M.D., COL, MC	**Facility:** DDEAMC
Dept/Svc: Surgery/Ophthalmology	**Associate Investigators:** Tonya Pavlovic, M.D., CPT, MC Kenneth Y. Gleitsmann, M.D., CPT, MC
Key Words: Intraocular Lens, Implant, Ophthalmology, Aphakia, Surgery	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results** Mar 82 Continue

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Progress: 70 patients FY 81; 104 during this reporting period, for a total of 174. No complications reported.

Detail Summary Sheet

Date 22 Sep 82	Prot No.: 81-27	Status: Terminated

Title: Computer-Assisted Surgical Instruction.

Start Date: May 81	Est Comp Date: Sep 82
Principal Investigator: Fred H. Edwards, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Surgery	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To provide a means of surgical instruction that can be used at the convenience of the student.

Technical Approach: The Hewlett-Packard 9830A computer will be used. A series of general topics will be selected by the surgical staff. The programmer will develop clinical situations stressing major concepts pertaining to each topic. After reviewing the proposed clinical situations with the staff, the programmer will translate the situations into a computer program. This program can then be stored on a magnetic tape file for future use.

Progress: This work was terminated because of the lack of computer access. Users cannot use the computer during the day because it is used by Pathology; at night the area is locked.

Detail Summary Sheet

Date 22 September 1982 Prot No.: 81-28 Status: Terminated

Title: Computer-Aided Diagnosis of Acute Abdominal Conditions.

Start Date: May 81	Est Comp Date: Sep 82
Principal Investigator: Fred H. Edwards, M.D., CPT, MC	Facility: DDEAMC
Dept/Svc: Surgery	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To establish a computer program that will assist physicians in the diagnosis of acute abdominal pain.

Technical Approach:

Progress: This work was terminated because of the lack of computer access. Users cannot use the computer during the day because it is used by Pathology; at night the area is locked.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 82-13	Status: Ongoing

Title: The Efficacy of Single Dose of Metronidazole, Cefoxitin, or Placebo in Preventing Wound Infections Following Appendectomy.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: James A. Classen, M.D., CPT, MC		Facility: DDEAMC
Dept/Svc: Surgery		Associate Investigators: Ross S. Davies, M.D., COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Determine efficacy of single dose antibiotic in emergency appendectomy.

Technical Approach: Prospective, randomized, double-blind study.

Progress: 17 patients entered into study. No reportable data available.

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 82-15	Status: Completed

Title: Predictive Ability of Body CT Scan.

Start Date: Dec 81	**Est Comp Date:** Aug 82
Principal Investigator: Lester M. Dyke, M.D., CPT, MC	**Facility:** DDEAMC
Dept/Svc: Surgery	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To ascertain the predictive value of abdominal and thoracic CAT scanning with reference to pathology found at laparotomy and thoracotomy.

Technical Approach: Charts of patients who had received thoracic and abdominat CAT scanning in the past 18 months were reviewed. Those who had the procedure done as a preop diagnostic procedure had the interpretation compared to the postoperative diagnosis. The case was then relegated to one of four categories: true+, true-, false +, or false-.

Progress: The study was stopped upon fulfillment of the goals initially delineated.

Results:

true+	66%
true-	6%
false+	0%
false-	27%
	99%

Detail Summary Sheet

Date 21 Sep 82	Prot No.: 82-46	Status: Ongoing

Title: Selective Monocular Deprivation: An Electrophysiological Study.

Start Date: 20 Jul 82	**Est Comp Date:** Jan 83
Principal Investigator: Jeff Rabin, CPT, MSC	**Facility:** DDEAMC
Dept/Svc: Surgery/Optometry	**Associate Investigators:**
Key Words: Amblyopia, Astigmatism, Mondocular deprivation, Neural plasticity	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The intent of this study is to perform an objective, electrophysiological analysis of human amblyopia. The results will be compared to various physiological, anatomical and behavioral findings for animals exposed to the type of visual experience which leads to amblyopia in humans. An effort will be made to specify the area(s) of the brain affected in amblyopia, and a mechanism for the underlying changes in neural circuitry will be suggested.

Technical Approach: The Visual-Evoked Response (VER) will be recorded from scalp electrodes placed at the occipital cortex of human amblyopes. Each subject will have substantial astigmatism in the amblyopic eye, but very little in the dominant eye. It is assumed that unilateral astigmatism causes a selective (meridional) amblyopia for one orientation which may be detected with the VER. in addition, animal research suggest tht the dominant eye will exhibit a preference for the same orientation while the binocular response will be relatively enhanced for the orthogonal orientation. Confirmation of these predictions with the VER will corroborate the animal model of amblyopia suggesting that neural modifications also occur in the human visual cortex.

Progress: Nine subjects enrolled to date. Measurements for three control subjects who lack astigmatism indicate that: a) The binocular response is about 1.6x greater than the monocular response. b) The response is invariant with orientation. c) The response is quite sensitive to meridional defocus. In six subjects with unilateral astigmatism the VER was attenuated at the orientation of greatest astigmatic blur despite optimal vorrection. In addition, anisotropies were also detected when these subjects were tested with the dominant eye, and with both eyes. Although these results were quite variable, they offer support for a cortical impairment in human amblyopia. It is hoped that additional measurements will indicate a more consistent effect.

Detail Summary Sheet

Date 25 Oct 82	Prot No.: 82-57	Status: Ongoing

Title: Utilization of the Bascom Technique in the Treatment of Acute and Chronic Pilonidal Abscess Disease.

Start Date:		Est Comp Date:
Principal Investigator: Kerrey B. Buser, M.D., CPT, MC		**Facility:** DDEAMC
Dept/Svc: Surgery/General Surgery		**Associate Investigators:** Guillermo Quispe, M.D., MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results**

Study Objective: To ascertain if the application of the Bascom technique will decrease disability and/or hasten healing time in acute pilonidal disease.

Technical Approach: All acute and chronic pilonidal abscesses seen by the Surgical Service at DDEAMC are to be treated according to the techniques described by Dr. Bascom. The patients will be treated as outpatients. During duty hours, Dr. Buser and/or Dr Quispe will see all patients included in this study and will provide treatment. The patients will be seen at least once a week until total healing has taken place. At the completion of the study, disability time and healing time will be assessed and a comparison will be made with Dr. Bascom's results.

Progress: Study locally approved in Sep 82, no reportable data available.

Detail Summary Sheet

Date 1 Oct 82	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Nov 80	Est Comp Date:
Principal Investigator: Thomas W. Grabow, M.D., LTC, MC	Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Mar 82 Continue

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of the Teunant Anchor Anterior Chamber Lens.

Progress: Number of subjects FY 82: 94; total to date: 143. 96% - 20/30 vision or better.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 79-25	Status: Ongoing

Title: The Effect of Guaifenesin in the Treatment of Middle Ear Effusion: A Double Blind Study.

Start Date: Nov 80		Est Comp Date:
Principal Investigator: Gregory H. Blake, M.D., CPT, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether guaifenesin, a mucolytic agent has a place in the management of middle ear effusion.

Technical Approach: The study is a double blind protocol looking at children aged 2-16 years who have middle ear effusion. Middle ear effusion is diagnosed by clinical history, otoscopic exam, and audiology evaluation. Audiologic criteria are a Type B tympanogram or two of the followingA a difference between air and bone conduction hearing threshold level of .15 dB or more on three test frequencies; a maximum compliance change peak which is negatively displaced 100 mm or more from ambient air; and a static middle ear compliance less than 0.26 ml. Half of those patients agreeing to enter the study will be given guaifenesin and the other half the base of guaifenesin. Patients will be followed for clinical and audiologic improvement at two and four weeks.

Progress: 12 subjects enrolled to date. Still collecting subjects. No adverse drug reactions.

Detail Summary Sheet

Date 28 Sep 82	Prot No.: 80-31	Status: Terminated

Title: Medical Screen and Functional Testing in a Pilot Cohort of Over Age Forty Active Duty Army Personnel to be Trained and Tested in the New Army "Over Forty Physical Training Program."

Start Date: Oct 80		Est Comp Date:
Principal Investigator: Ronald Albright, M.D., CPT, MC		Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Medicine		Associate Investigators: Milton D. Alexander, M.D., MAJ, MC DDEAMC; Kent M. Plowman, M.D., MAJ, MC DDEAMC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The purpose of this protocol is to attempt to identify latent coronary artery disease (CAD) in asymptomatic active duty military personnel prior to conditioning training. Multiple serial screening procedures will be used to ascertain the safety of aerobic testing/training in individuals over forty years of age, regardless of their initial state of conditioning.

Technical Approach: The strategy proposed is to validate existing screening tests that have been applied to other groups of military personnel. A pilot group will be tested relatively intensively with the intent of identifying the combination of screening procedures having the sensitivity, specificity and predictive value necessary to identify a subgroup of individuals at increased risk of cardiac disorders requiring definitive evaluation. A serial screening strategy will be tested as to its sensitivity, specificity, and predictive value. Projections can then be made for the materiel and personnel costs required for an Army-wide screening program prior to cardiovascular fitness testing of all active duty members over age forty.

Progress: Project is ongoing at present with ongoing evaluation of data diverted through TSGO. Results of initial project have been collated through TSGO. Data have been combined with the merger Army-wide project of evaluating over 40 year old males for PT testing.

Total number enrolled: 300 AD males. No adverse reactions.

Detail Summary Sheet

Date 1 Oct 82	Prot No.: 80-35	Status: Terminated

Title: A Multi-Clinic, Double-Blind Evaluation of Butibel Tablets vs Sodium Butabarbital vs Belladonna Extract vs Placebo in the Treatment of Irritable Bowel Syndrome

Start Date: Apr 81	Est Comp Date: Mar 82
Principal Investigator: Melvin Butler, M.D., COL, MC	Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Medicine	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the efficacy, if any, of Butibel in the treatment of Irritable Bowel Syndrome.

Technical Approach: This study is being done in a double-blind fashion.

Progress: Number of subjects enrolled: 14. No adverse reactions. Study terminated due to PCS of investigator.

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 81-12	Status: Ongoing

Title: Comparison of Single-Dose Metronidazole versus Seven Day Metronidazole in patients with Hemophilus Vaginalis Vaginitis.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: John L. Larson, M.D., MAJ, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators: Gregory H. Blake, M.D., CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the efficacy of single dose metronidazole in the treatment of H. vaginalis vaginitis.

Technical Approach: Double-blind clinical trial looking at 100 women age 18-44. Women that are pregnant, have diabetes or blood dyscrasia or other than non-specific vaginal infections will be excluded. A questionnaire will be filled out and exam performed. Patients will be randomly assigned to treatment or placebo group. Followup at 7 and 28 days.

Progress: Six subjects enrolled. No reportable data available.

Detail Summary Sheet

Date 28 Sep 82	Prot No.: 81-25	Status: Terminated
Title: Multicenter Outpatient Trial of Topical DMSO Gel (35% & 70%) in the Short-Term Treatment of Acute Musculoskeletal Strains and Sprains and Other Acute Traumatic Musculoskeletal Conditions.		
Start Date: Jun 81		Est Comp Date: Apr 82
Principal Investigator: Leroy R. Fullerton, M.D., LTC, MC		Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Surgery/Orthopedic		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the effectiveness of DMSO in strengths of 35% and 70%.

Technical Approach: Apply DMSO gel and follow signs and symptoms.

Progress: Total number of subjects: 40. There were no adverse reactions. Study terminated by Wallace Laboratories; results of double blind study not yet available from them.

Detail Summary Sheet

Date 1 Oct 82	Prot No.: 82-23	Status: Ongoing

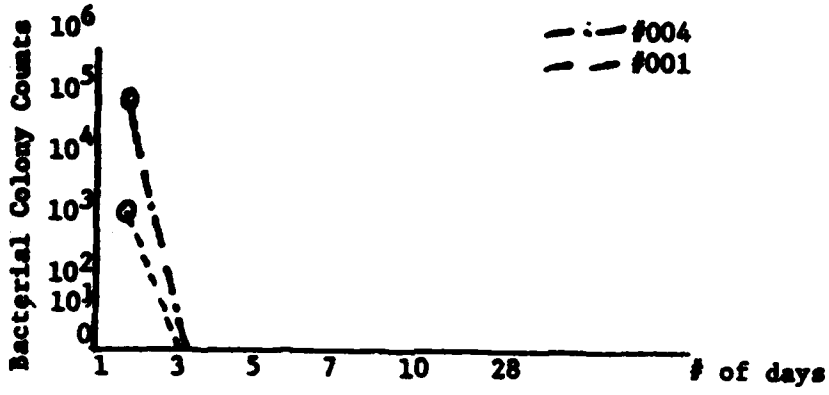
Title: Effect of Hydration, Urine Acidification and Pyridium (HAP) on Bacterial Count in Lower Urinary Tract Bacterial Infections (LUTBI).

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Magdi B. Hanna, M.D., CPT, MC		Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators:
Key Words: LUTBI-Lower Urinary Tract Bacterial Infection HAP-Hydration, Acidification & Pyridium		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: This study was undertaken with the objective of proving the efficacy of a regimen to treat LUTBI that did not require the use of antibiotics.

Technical Approach: Female patients age 18-40 presenting to the Family Practice Clinic at Martin Army Community Hospital with symptoms of internal dysuria with urinary frequency <72 hours, and who did not meet any of the exclusion criteria; were assigned through a double blind approach to one of two groups of treatment. The first group received Amoxicillin 500 mg, 6 tabs one dose + pyridium 100mg, 2 tabs tid x 5 dosages + placebo + p.o. qid x 7d. The second group received 6 placebo tabs one dose initially + pyridium as with the first group + vitamin C 500 mg p.o. qid x 7d + instructions to increase water intake to 12 fl oz 8 x 1d. Diagnostic criteria for inclusion required unspun urine of patient with $\geq$ 2 bacteria/OIF and $\geq$ 2 WBC/HPF. Urines were cultured and U/A repeated on days 1,3,5,7, 10 and 28.

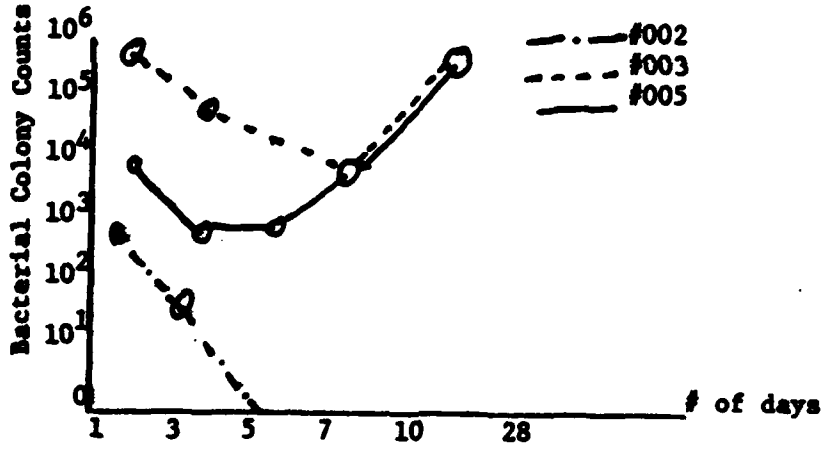
Progress: Only 5 patients have been included in the study so far. The results are summarized in graphs A&B. At this stage it is too early to make any definite conclusions. It is obvious that single dose Amoxicillin is effective in the treatment of LUTBI. Also, it seems evident that HAP is effective in lowering bacterial colony counts in infected urines. Whether or not HAP alone will be sufficient to treat LUTBI might depend on the initial bacterial colony count which varies from patient to patient. This is still to be shown by further patient enrollment in the study. No adverse reactions.



Graph A: Single Dose Amoxycillin

Graph A represents the effect of single dose Amoxicillin on the bacterial colony counts in urines of 2 patients included in the study.

Graph B represents the effect of Hydration, urine acidification, and pyridium (HAP) on the bacterial colony counts of infected urines of 3 other subjects included in the study. Each curve represents the course of a single patient identified by their LUTBI-HAP I.D. #.



Graph B: HAP Treatment

Detail Summary Sheet

Date 18 Oct 82	Prot No.: 82-24	Status: Ongoing

Title: The Efficacy of Education on Training Time Lost Due to Tobacco Related Illnesses.

Start Date: Jan 82		Est Comp Date:
Principal Investigator: Gregory H. Blake, M.D., CPT, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators: Wayne G. Stanley, M.D., CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: To determine whether an educational process, in this case a slide series, can modify behavior related to tobacco use. Also to determine whether tobacco use adversely affects the amount of time a soldier in BCT is involved in training.

Technical Approach: A questionnaire was given to six companies (240 men ea) to determine smoking habits. Two companies were evaluated each week. One received a talk on tobacco use and the other acted as a control. All TMC visits and hospitalizations were evaluated and recorded if discharged from the facility as a URI, bronchitis, sinusitis or pneumonic. All profiles were recorded. Data was evaluated according to whether soldiers were smokers and whether they received the talk. A repeat questionnaire was given to those completing BCT to determine changes in smoking habits.

Progress: Questionnaire portion completed; pending complete analysis of data.

Detail Summary Sheet

Date 1 Oct 82	Prot No.: 82-36	Status: Ongoing

Title: Efficacy of a Clinically Directed Lecture Series in Changing Patterns of Caring for Hypertensive Patients.

Start Date: Mar 82		Est Comp Date: Nov 82
Principal Investigator: Larry S. Fields, M.D., MAJ, MC		Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: To assess performance of management of hypertension after an in-depth course.

Technical Approach: Chart audit of before and after the course clinic visits for hypertension using specified criteria.

Progress: All data collected. Statistical analysis of data initiated, but not compiled.

Detail Summary Sheet

Date 1 Oct 82	Prot No.: 82-37	Status: Ongoing

Title: Comparison of Two Modes of Therapy in Acute, Uncomplicated Bronchitis.

Start Date: Mar 82	**Est Comp Date:**
Principal Investigator: Edward M. Friedler, M.D., CPT, MC	**Facility:** Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	**Associate Investigators:** Danny P. Kaup, M.D., MAJ, MC John C. Lincoln, III, M.D., CPT, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine efficacy of antibiotics in effecting hospitalization in soldiers with bronchitis.

Technical Approach: Randomized double-blind placebo/antibiotic prospective clinical trial.

Progress: Number of subjects enrolled: 54. No adverse reactions. All data collected. Statistics completed, but not compiled.

Detail Summary Sheet

Date 1 Oct 82	Prot No.: 82-41	Status: Ongoing

Title: Correction of Myopia Using the Fading Technique.

Start Date: May 82		Est Comp Date:
Principal Investigator: Glenn C. Griffiths, M.D., CPT, MC		Facility: Martin Army Hospital USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice, Opthalmology, Optometry		Associate Investigators: Thomas W. Grabow, M.D., LTC, MC William T. Nimmons, O.D., CPT, MSC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if training the eye to focus at progressively greater distances results in improvement in myopia.

Technical Approach:
1. Test visual parameters of subjects.
2. Subjects begin fading technique using lens system.
3. Vision testing 3 days per week.
4. Retest visual parameters of subjects at 6 and 12 months after training completed.

Progress: Money for purchasing lenses and vision charts obtained. Now awaiting purchase of lenses through Comptroller's Office.
Number of subjects enrolled to date: 0.

Detail Summary Sheet

Date 14 Oct 82	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Oct 81		**Est Comp Date:**
Principal Investigator: Donald A. Schlomer, M.D., CPT, MC		**Facility:** USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/Ophthalmology		**Associate Investigators:**
Key Words:		
Accumulative MEDCASE Cost:	**Est Accumulative OMA Cost:**	**Periodic Review Results** Mar 82 Continue

Study Objective: To provide to cataract patients the latest development in ophthalmology concerning the correction of aphakia vision. The technical approach

Technical Approach: An intracapsular cataract extraction was performed followed by insertion of a Tennant Anterior Chamber Intraocular Lens.

Progress: A total of 14 patients were operated on during the reporting date. There were no complications noted from the intraocular lens. All patients, who are far enough out of from their surgery to check, are seeing 20/20 out of the operated eye with spectacle correction.

Detail Summary Sheet

Date 12 Oct 82	Prot No.: 81-13	Status: Terminated

Title: Evaluation of Live, Attenuated, Intranasally Administered Vaccines in Open Trials in Young Children.

Start Date: Dec 81	**Est Comp Date:** Spring 1982
Principal Investigator: Robert A. Walker, M.D., LTC, MC	**Facility:** USA MEDDAC, Ft Campbell, KY
Dept/Svc: Pediatrics	**Associate Investigators:** Bruce E. Willham, M.D., CPT, MC Peter F. Wright, M.D., Vanderbilt Univ Medical Center
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Attempt to determine if the two cold-adapted vaccine strains which share the same attenuated genes from the master A/Ann Arbor/6/60 strain have the same level of infectivity and clinical safety. Will any minor reproducible pattern of clinical illness emerge when vaccines are given on a larger scale? Can the vaccines be shown protective against homologous or related naturally circulating strains?

Technical Approach: Nasal administration of either A/USSR or A/ALASKA live, attenuated viral vaccines to well children 1-3 years of age. Follow up visits on day 3,6, 1 month and after flue season. Blood is drawn on day of vaccine, one month later and after flu season. Throat cultures are done days 0, 3 and 6.

Progress: 20 children enrolled total; no adverse drug reactions. This study was being conducted with the principal investigator being LTC Robert A. Walker, who has since resigned from active duty. No progress was made from the time of the last annual report. After Dr. Walker left we at Ft Campbell (C, Ped Clinic and C, Prof Svcs/Dep CDR) tried to carry on and complete this study. We identified a need for a part-time individual to help with enrolling potential study members, in contacting parents of eligible children, counselling them, keeping records, etc. This was necessary because no one on staff has sufficient time to do these time consuming tasks due to our large workload. We sought funding from both R&D Command and CID at HSC. After multiple telephone contacts with no apparent chance of obtaining funds in the time period needed we decided we could no longer entertain the idea of completing this study. Therefore, the study has been terminated.

Detail Summary Sheet

Date 28 Sep 82	Prot No.: 81-26	Status: Terminated

Title: Three-Way Double-Blind Efficacy Trial of Topical 35% DMSO Gel and 70% DMSO Gel vs 1% DMSO Gel as Control in the Treatment of Acute Ankle Sprains.

Start Date: Jul 81		Est Comp Date: Feb 82
Principal Investigator: Stephen L. Frushour, M.D., LTC, MC		Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/Orthopedic		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Evaluate the effectiveness of DMSO in the treatment of moderate to severe ankle sprain.

Technical Approach: Topical application of drug TID. Clinical evaluation before, during and after application for one week. Drug and urine studies before and after application.

Progress: This study was terminated by the FDA and Wallace Laboratory in February 1982. Thirty-two patients were treated under this protocol. There were no technical, medical or administrative problems. There were no adverse reactions or complications. The reason for the termination of the project is unknown to this investigator.

Detail Summary Sheet

Date 1 Oct 82	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Jul 81	Est Comp Date:
Principal Investigator: Norman T. Byers, M.D., LTC, MC	Facility: Moncrief Army Hospital USA MEDDAC, Ft Jackson, SC
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Mar 82 Continue

Study Objective: Insertion in selected patients of Tennant Anterior Chamber Anchor Lens.

Technical Approach: Using routine intracapsular cataract techniques, the lens would be inserted prior to final closure of the wound.

Progress: Number of subjects this reporting period: 16; total to date: 20. In FY 82 two procedures were aborted due to positive vitreous pressure and the patients had a routine intracapsular cataract extraction. The other 14 patients had successful insertion of the intraocular lens with good results. One patient has had a retinal detachment which is in the stage of being repaired. Approximately 50% of all cataract patients are having the lenses inserted, as per FDA protocol. We will continue to be using the Tennant Anterior Chamber Anchor Lens as we have been very pleased with our success at Ft Jackson.

Detail Summary Sheet

Date 14 Oct 82	Prot No.: 82-22	Status: Ongoing

Title: Infant Rotavirus Diarrhea Study.

Start Date: Dec 81		Est Comp Date:
Principal Investigator: James J. Gibson, M.D., DAC		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Pediatrics		Associate Investigators: Jack A. Rogers, Jr., M.D., LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: To identify epidemiologic characteristics of infant diarrhea caused by the rotavirus.

Technical Approach: Children less than 48 months of age with gastroenteritis were enrolled in this study. Age matched controls were also enrolled. Children studied were characterized by a questionaire and had a stool specimen studied for rotavirus by ELISA testing and the feces were also cultured for bacterial pathogens.

Progress: 121 Children were enrolled in the study. Of these, 41 were enrolled from the Moncrief Army Hospital Pediatric Clinic patient population. No injuries to patients occurred. No drugs were used in this study and no adverse reactions were observed. Data from the cohorts at Richland Memorial Hospital and Moncrief Army Hospital were combined and analyzed. Briefly the data support the following observations: 1) Case-control evidence suggests breast feeding is protective. 2) Rotavirus cases were less likely to have siblings under 5 years of age. 3) Rotavirus cases were less likely to have siblings in school or in day care. 4) Rotavirus cases were less to be in day care themselves. 5) Rotavirus positive and negative diarrhea cases were more likely to have another family member ill in the prior 7 days (at a significantly higher rate than controls).

We interpret the data gathered thus far to indicate that rotavirus gastroenteritis is not usually spread from toddler to toddler, nor from school age sibling to the index case, but, rather, is brought home to the infant by adult family members with mild non-primary infections. The study is being evaluated to determine if, as designed, continued enrollment of cases and controls will yield additional information.

Detail Summary Sheet

Date 14 Oct 82	Prot No.: 82-39	Status: Terminated

Title: The Effect of Breast Feeding on Human Infectious Gastroenteritis.

Start Date: Mar 82		Est Comp Date: Sep 82
Principal Investigator: Jack A. Rogers, M.D., LTC, MC		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Pediatrics		Associate Investigators: James J. Gibson, M.D. Barbara Burkett, M.S.
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The objective of this study was to see if breast feeding afforded protection from rotavirus diarrhea.

Technical Approach: Birth records and well-baby clinic charts were reviewed to identify infants who were being breast fed and others to serve as controls. Approximately 250 records records were reviewed. Approximately 40 infants were identified as being breast fed. Thirty were contacted telephoically and indicated an interest in participating in the study. Questionaires were mailed to these subjects. Eight were returned marked "undeliverable at indicated address" and four were returned with the consent form and questionaire completed. Of the remainder, no answer was received.

Progress: Four patients were enrolled. The study was terminated because a cohort to be studied could not be obtained.

Detail Summary Sheet

Date 22 Sep 82	Prot No.: 81-38	Status: Completed

Title: A Double-Masked Study to Compare the Effect of a Combination Vasoconstrictor/Antihistamine with the Individual Components and Control Group on Redness and Itching Associated with Allergic Conjunctivitis

Start Date: Oct 81	**Est Comp Date:** Nov 81
Principal Investigator: Michael B. Hanna, M.D., DAC	**Facility:** USA MEDDAC, Ft McClellan, AL
Dept/Svc: Surgery/Ophthalmology	**Associate Investigators:**
Key Words:	

Accumulative MEDCASE Cost:	**Est Accumulative CMA Cost:**	**Periodic Review Results**

Study Objective: To compare the therapeutic effects of antihistaminic and decongestant eye drops alone or in combination and their effect in relieving the symptoms in cases of allergic conjunctivitis.

Technical Approach: The volunteers in this study were divided into four groups. The first received antihistimine drops only, the second received decongestant drops only, the third received a combination of both, and the fourth received placebo drops. The results were verified by clinical and laboratory techniques including conjunctival scrapings and were tabulated accordingly.

Progress: The examination and evaluation was carried out on five volunteers at the EENT Clinic of Noble Army Hospital. The presence of active conjunctival inflamation in all cases was verified. Its allergic nature was proven by clinical and laboratory studies. The reaction of the inflamation to the local administration of the drops was verified as mentioned above. The total number of cases in study reached 32 which was considered by the investigator and the company carrying out the research to be a sufficient number to be dealt with by one investigation and so the study was terminated. The results of the study, carried out by 20 other investigators all over the country, have not yet been published.

Detail Summary Sheet

Date 27 Oct 82	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Oct 80	**Est Comp Date:**
Principal Investigator: Nicholas E. Barreca, M.D., COL, MC	**Facility:** USA MEDDAC, Ft Rucker, AL
Dept/Svc: Surgery/Ophthalmology	**Associate Investigators:** Jimmy Carter, M.D., LTC, MC
Key Words: Intraocular Lens, Aphakia, Implant, Surgery, Ophthalmology	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results: Mar 82 Continue

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Progress: FY 81 - 15 implants; FY 82 - 32 implants; total to date - 47. For this reporting period Dr. Barreca implanted a total of nine intraocular lenses. Ten implants were attempted but one had to be aborted due to trouble with vitreous pressure. This patient was eventually contact lens corrected. However, this same patient, a year later, developed a rhegmatogenous retinal detachment, probably related to vitreous loss at the time of surgery. Of eight successfully implanted patients, five were posterior chamber lenses and three were anterior chamber lenses. One of the anterior chamber lenses was a secondary implant. Viscual acuities for all these patients have been 20/30 or better in all cases. There was a second patient who was not implanted due to a posterior capsular rupture during extra-capsular cataract extraction. There was limited vitreous loss and as a result, no lens was implanted. This patient was also contact lens corrected and has done well. Another patient who underwent anterior chamber lens implantation has developed a posterior capsular membrane which will require pars plana membranectomy. This patient has also had an anterior chamber lens that tended to rotate whenever the pupil was dilated. When the pupil is at its normal position or under the effects of miotics, the lens stabilizes. This patient will ultimately be rehabilitated back to normal vision after the pars plana membranectomy. A patient from the previous report had a lens in which the proximal loop, or superior loop, somehow became dislocated into the wound and healed there approximately six to seven weeks postoperatively. Recently, an attempt was made to remove this lens without success, so the lens was re-positioned. This case also required pars plana vitrectomy. The patient's vision is currently poor as a result of suture-induced astigmatism which may be relieved at a later date when the sutures are cut. Copies of the preoperative and operative reports as well as the adjunct safety study follow-up evaluation flow sheets, in each case, are forwarded to the company.

78-14 Ft Rucker, AL - Continued

Dr. Carter implanted 23 lenses during the reporting period. He implanted 15 posterior chamber lenses, six anterior chamber lenses, and two anterior chambers as a secondary implant. His patients are in various degrees of follow-up with visual acuities ranging from 20/20 to 20/300. The majority of his patients have visual acuities 20/50 or better but have not undergone final follow-up visits. One or two patients have developed persistent corneal edema and may require penetrating keratoplasties in the future. Again, the preoperative, operative, and follow-up evaluation flow sheets are forwarded to the company.

At present, we continue to implant the Leiske Style-10 anterior chamber lens and both the Style 17-A and Style 20 posterior chamber lenses. These lenses have been highly satisfactory in our experience.

Overall, the majority of patients have achieved good postoperative visual acuities with minimal postoperative complications. There are three or four patients out of the total who have had an unfavorable result as referred to above. It is expected that there will be a trend toward implanting primarily posterior chamber lenses as the extracapsular cataract extraction technique becomes the preferred method of cataract extraction.

Detail Summary Sheet

Date 28 Oct 82	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Sep 82		Est Comp Date:
Principal Investigator: Ruben Orillac, M.D., DAC		Facility: Gorgas Army Hospital USA MEDDAC Panama
Dept/Svc: Surgery/Ophthalmology		Associate Investigators: Jerry D. Harrell, M.D.,COL,MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Progress: Investigators locally approved Sep 82. No reportable data available.

Detail Summary Sheet

Date 3 Nov 82 | Prot No.: 81-39 | Status: Ongoing

Title: Long-term Suppression of Atrophie Blanche With Use of Phenformin.

Start Date: Sep 81	Est Comp Date:
Principal Investigator: Robert B. Blumer, M.D., COL, MC	Facility: USA MEDDAC Panama
Dept/Svc: Medicine	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative CMA Cost:	Periodic Review Results

Study Objective: To continue to suppress Atrophie Blanche in a patient placed and controlled on Phenformin and Ethylestrenol therapy since September 1972.

Technical Approach: Only one patient will comprise the investigation. The patient is selected because of well documented medical history of the disease Atrophie Blanche to include publication of the circumstances and treatment of this specific case in Archives of Dermatology, Vol 109, May 1974, pages 664-666 (Case 5). Additionally, the treatment regimen to be employed has been successfully ongoing since 1972.

Progress: A single patient has been enrolled who continues on Phenformin. Her condition appears to require both the drug and a temperate climate for improvement.

AUTHOR INDEX

SUBJECT INDEX